EmbryoViewer™

User manual

UNISENSE® FERTILITECH

Caution: Federal law restricts this device to the sale on the order of a physician

EmbryoViewer 3.0

User manual v3.0

1 IMPORTANT restrictions and warnings

The following restrictions and warnings shall ensure safe and correct use of the EmbryoViewer™ by qualified personnel in a Fertility Clinic. The EmbryoViewer™ is used together with the EmbryoScope™ to select viable embryos for transfer in a fertility treatment. Proper evaluation and selection of embryos for transfer is essential to provide a successful treatment to patients. All personnel using the EmbryoViewer™ must therefore agree to read and understand this user manual, must observe the restrictions on use, and heed the warnings below to be allowed to operate the EmbryoViewer™.

Restrictions on use
• The EmbryoViewer™ may only be used by qualified personnel trained by Unisense FertiliTech A/S employees. • Users should contact Unisense FertiliTech A/S immediately to report any incident and/or injury to a patient, operator, or maintenance employee that occurred as a direct or indirect result of operating the EmbryoViewer™. • Access to the EmbryoViewer™ must be controlled, so that only qualified trained personnel have access to the EmbryoViewer™. Untrained personnel could inadvertently change the annotation or selection of embryos, so it is essential that the EmbryoViewer™ is installed in a secure place not accessible by patients or the public. • While the EmbryoScope™ facilitates safe handling and access to information about the embryos in a particular treatment, it can only supplement and NEVER replace proper security measures to ensure that embryos selected and transferred belong to the proper patients. All standard procedures for labeling and validation of identity for EVERY transfer of gametes and embryos between vessels MUST be maintained. • Upload of data to Unisense FertiliTech A/S is a service to fertility clinics to facilitate quality control and off site quality check of instrument performance. It may only be initiated IF THIS IS PERMISSIBLE BY LAW AND REGULATIONS in the country where the EmbryoViewer™ resides • The clinic shall be solely responsible for ensuring that all local rules and regulations are observed in connection with the upload of data to Unisense FertiliTech A/S and that patients are informed about such upload of data. • Only anonymous data may be uploaded to Unisense FertiliTech A/S. PATIENT ID MAY ONLY BE UPLOADED IF THE ID NUMBER IS AN INTERNAL NUMBER USED BY THE FERTILITY CLINIC. If the patient ID is a social security number or any other traceable personal ID number it may NOT be uploaded to Unisense FertiliTech A/S. • The data received by the EmbryoViewer™ workstation about the

performance of the EmbryoScope™ instrument cannot replace an actual monitoring of the EmbryoScope™ instrument. The performance of the EmbryoScope™ - Embryo Monitoring System must therefore be checked on a regular basis through control of the EmbryoScope™ itself.

Warning

- The device may only be operated by trained personnel. Only trained personnel may annotate and select embryos, as personnel that are not properly trained could inadvertently or deliberately change the embryos that are selected for transfer.
- It is essential that the identity of embryos selected for transfer is rigorously checked before transfer from the EmbryoSlide™ to the transfer catheter. The appearance of the embryo in the microscope used for loading the embryo in the catheter MUST match the appearance of the embryo on the last acquired image as printed out on the laboratory data report. The patient ID and patient name on the laboratory data Report, MUST match the label on the EmbryoSlide™ AND the label on the catheter.
- Backup of image and patient data MUST be performed at regular intervals. Automated nightly backups to a safe external hard disc can be implemented through a selection in the settings tab.
- The clinic shall be solely responsible for ensuring that all local rules and regulations are observed in connection with the upload of data to Unisense FertiliTech A/S and that patients are informed about such upload of data.

Installation and maintenance

- Installation, inspection, adjustment and wiring of the EmbryoViewer™ can only be carried out by a certified Unisense FertiliTech A/S employee.
- The EmbryoViewer™ shall remain at the location where it was installed by a Unisense FertiliTech A/S employee and may only be moved by Unisense FertiliTech A/S personnel or upon explicit authorization in writing.

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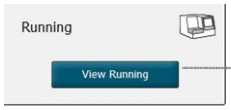
2 Quick guide

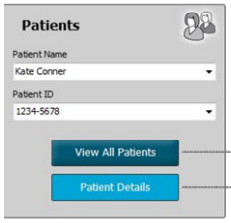
The main navigation tool in the EmbryoViewer™ is the navigation panel (left part of the screen). The navigation panel is fixed on all pages, allowing for easy navigation between different functions and views. The manual is structured according to the functions (buttons) in the navigation panel.

2.1 Overview of functions in the navigation panel



→ Running instruments

View all running slides from all connected EmbryoScopes™



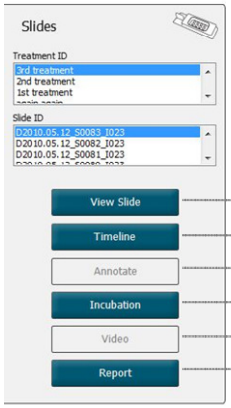
→ Patient information

Patient Name

Patient ID

Lists all patients including patient details

Shows detailed patient information including e.g. diagnosis, medication and outcome data



→ Slide and embryo details

Treatment ID (if a patient has several treatments, these are shown)

Slide ID (if several slides belong to the same patient, these are shown)

Shows time-lapse films of embryos from the specific slide

Shows embryos from the specific slide in a timeline view

Detailed view of embryos for annotation of e.g. cleavage times

Running conditions for the specific slide e.g. incubation temperature and gas concentration

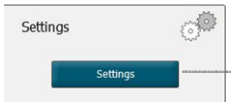
Exports video sequences and single images

Generates report sheets; laboratory data, instrument data, patient information

→ Database of all acquired data

Lists all slides including data on e.g. fertilization time, primary outcome data and instrument QC status

Lists all slides and primary running conditions for each slide



→ Backup and upload of data

Backup of data and upload of data to Unisense FertiliTech A/S

2.2 Association between different ID's

Several ID's are used in EmbryoScope™ and EmbryoViewer™ data. Below is a description of the different ID levels and a figure showing an overview of the association between the patient ID, treatment ID, slide ID and embryo ID. For detailed information on how to link patient ID to treatment and slide ID, see section 5.2.11.

Patient name and ID

Patient name and ID number can be written into the patient file both on the EmbryoScope and on the EmbryoViewer. Adding a slide on the EmbryoScope creates a new patient with the patient information written on the EmbryoScope. A new patient can also be created on the EmbryoViewer, and adding a slide in the EmbryoScope with the same patient information links the patient information from the EmbryoViewer to the slide started on the EmbryoScope.

Treatment ID

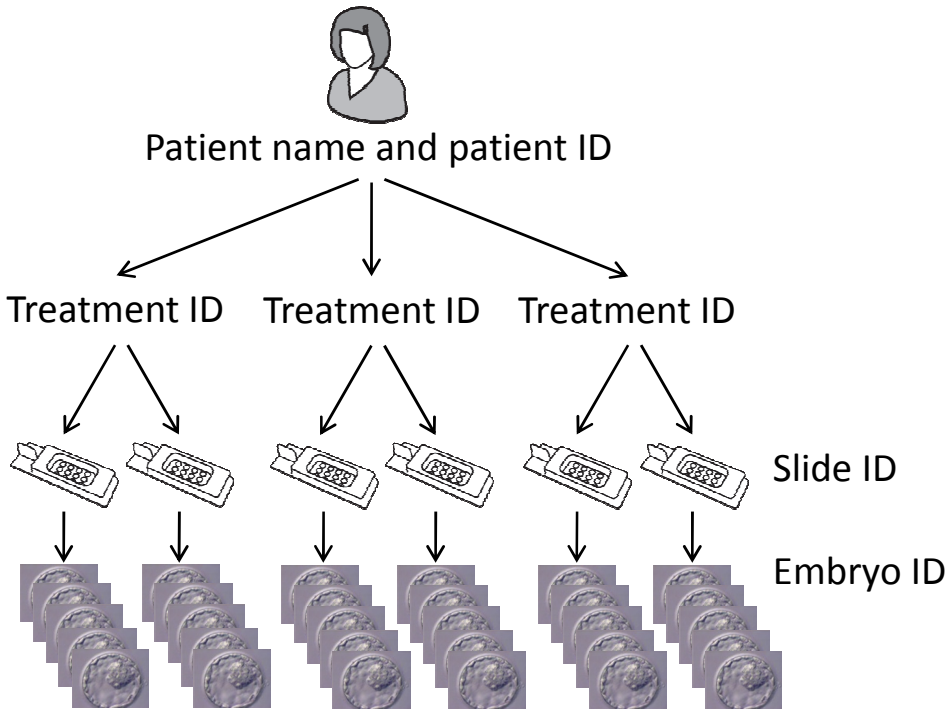
Each patient has one to several treatments. The treatment is always named "Unknown" when a slide is started. The treatment can be renamed so it is possible to distinguish between succeeding treatments.

Slide ID

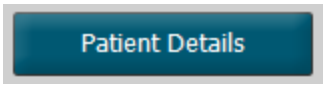
Each slide has a unique number consisting of date, slide and instrument number. Slides can be reallocated to treatments using the "Patient Details" page.

Embryo ID

Each embryo has an ID number which is created when a slide is added on the EmbryoScope. The embryo ID is shown on the "Annotate" page in the blue header bar, on the "Patient Details" page and on the Laboratory Report page.

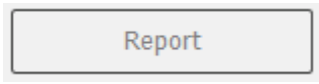


2.3 Colour guide



Available but not selected/active button or frame

Selected/active button or frame



Disabled button, appears dark blue when the function can be used

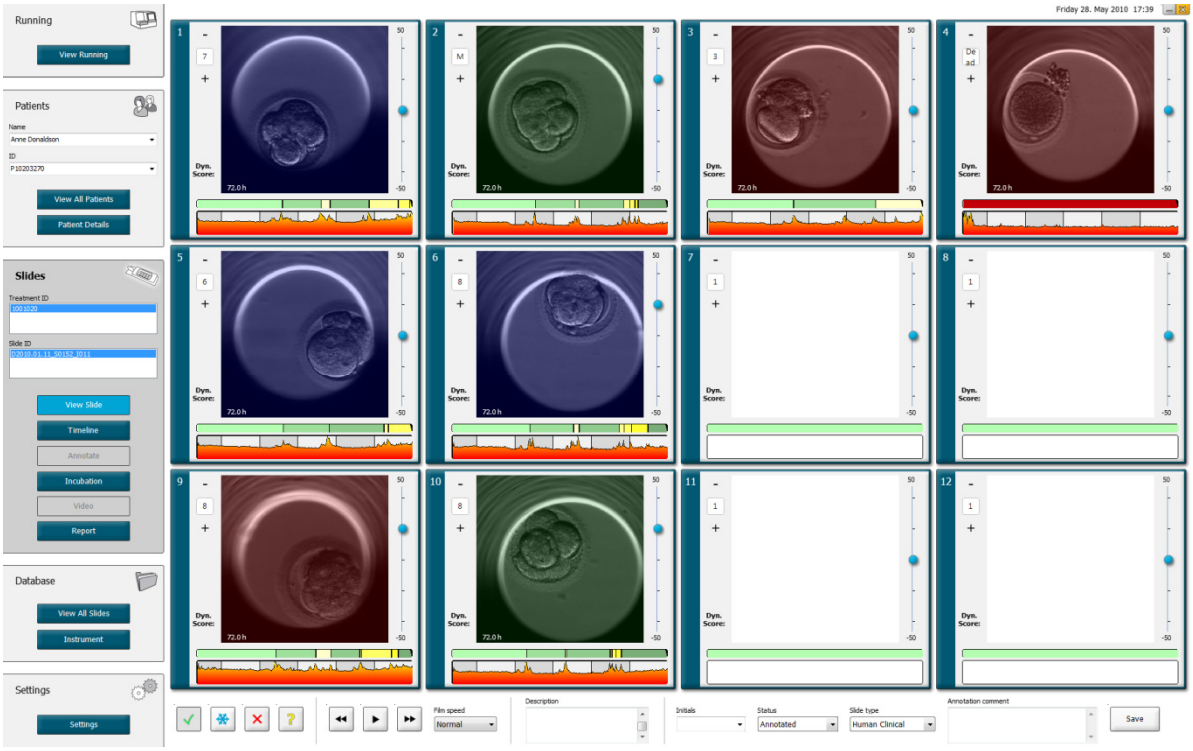
2.4 View time-lapse and score embryos

A quick guide on how to view time-lapse videos and score embryos is presented below. For a more detailed description and explanations of all functions see section 6.

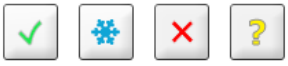
2.4.1 Time-lapse of all embryos

Click

and images of all embryos in the active slide are shown.

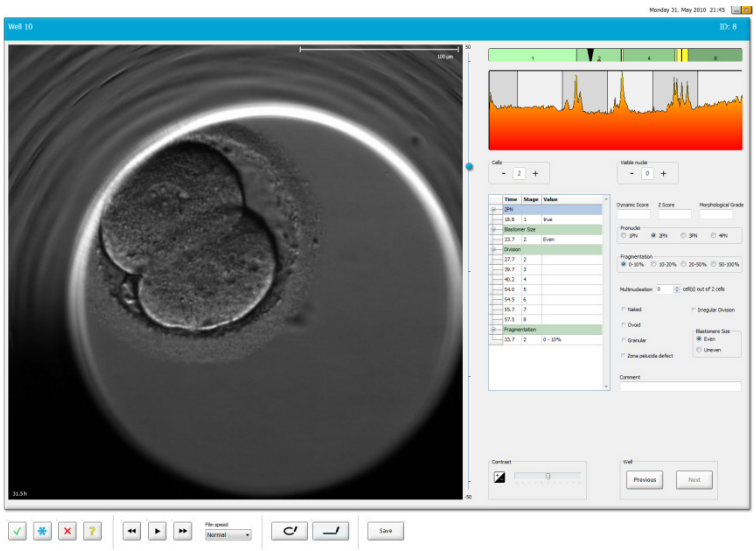


Play the time-lapse images using or the scroll wheel.

Select embryos for transfer, freeze, discarding or later decision using  , marking the embryos green, blue, red or yellow.

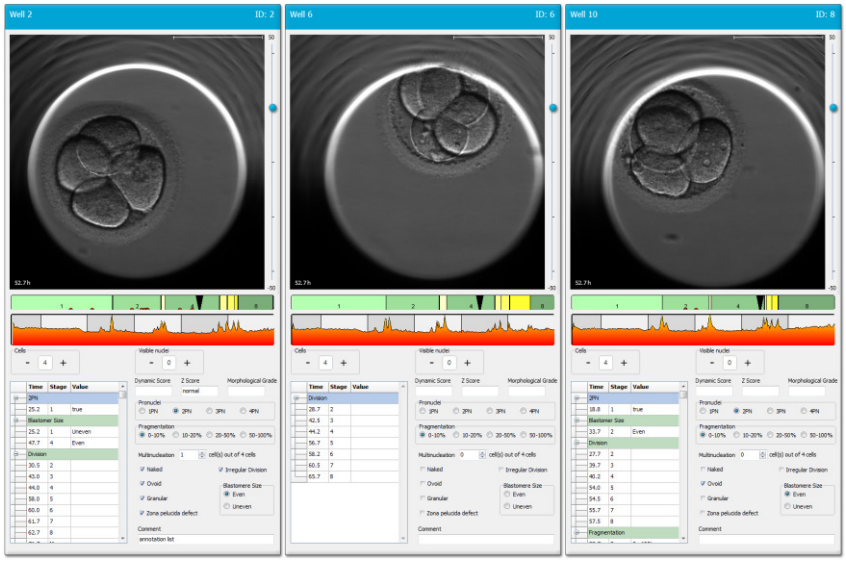
2.4.2 Time-lapse image series of a single embryo

To view a single enlarged embryo time-lapse film select the embryo by double-clicking on the embryo frame. Detailed annotation tools appear, for more information on the annotation tools see section 6.3.



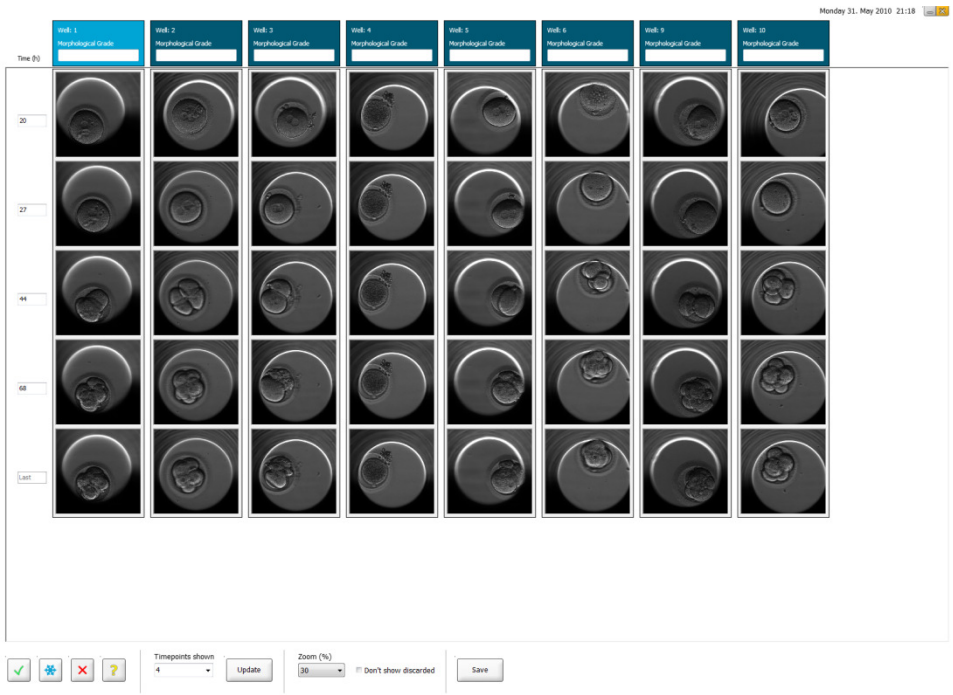
2.4.3 Time-lapse of several selected embryos

Select 2 or 3 embryos in View Slide (the dark blue frame turns light blue when the embryo is selected) and click Annotate. All selected embryos are shown including the annotation tools.



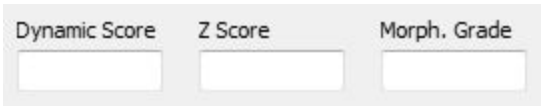
2.4.4 Embryo development at specific time points

Click the Timeline button to display the embryos within the specific slide at specified time points. The morphological grade can be typed in at the top of each embryo timeline view. The morphological grade is also shown in the “Annotate” page.



2.4.5 Grading embryos

The time-lapse inspection and annotation tools assist the embryologist in selecting the best embryos for transfer and freeze. The embryo grade or score can be saved using the boxes shown below. For explanation of the “Dynamic Score”, “Z Score”, and “Morphological Grade” see section 6.3.4.



3 Introduction

3.1 EmbryoViewer™ introduction

The purpose of the EmbryoViewer™ workstation is to assist the embryologist in selecting the best embryos. The EmbryoViewer™ does not perform any diagnostics, but only shows data from the EmbryoScope™ and data typed in by the user. The EmbryoViewer™ assists the user in selecting the best embryos by allowing for inspection of high resolution time-lapse images of embryo development, detailed annotation tools and inspection of EmbryoScope™ running conditions.

The EmbryoViewer™ workstation provides:

- High resolution time-lapse images of single embryos
- Embryo annotation tools assisting in selecting embryos
- Inspection of incubation details e.g. temperature and gas conditions
- Export of data for statistical analysis

The EmbryoViewer™ workstation is an accessory to the EmbryoScope™. The EmbryoScope™ provides a safe, controlled culture environment, while allowing continuous monitoring and observation of up to 72 embryos at a time.

Data from the EmbryoScope™ can be viewed in the EmbryoViewer™. This includes embryo images, incubation details, alarms, log files and other instrument parameters. The EmbryoViewer™ workstation can be used to review and compare synchronized time-lapse movies of different embryos.

In addition, the EmbryoViewer™ contains a simple database which enables the user to annotate time-lapse images for e.g. cleavage times, fragmentation, multinucleation, pronuclei and other characteristics used for selecting the best embryo. Annotations are saved in the database and can be exported to an Excel file for statistical analysis.

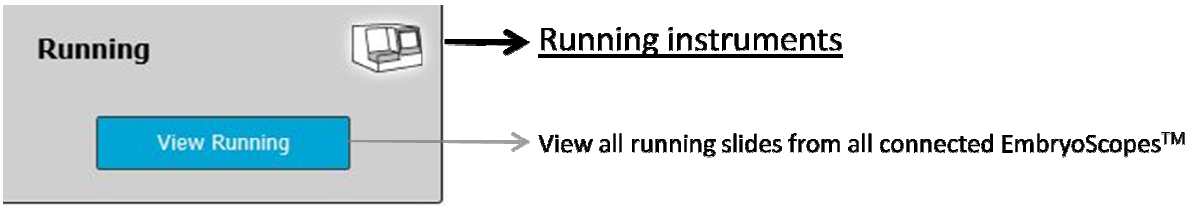
The EmbryoViewer™ also enables input of patient details, treatment data and outcome data. This data is also stored in the database and can be exported with annotations to an Excel file.

Important
The EmbryoViewer™ software does not control any hardware components in the EmbryoScope™ and thus has no influence on the incubation of embryos. If the EmbryoViewer™ fails or is shut down by e.g. a power failure, the EmbryoScope™ continues to run and data is saved on the EmbryoScope™

3.2 Instruction and installation

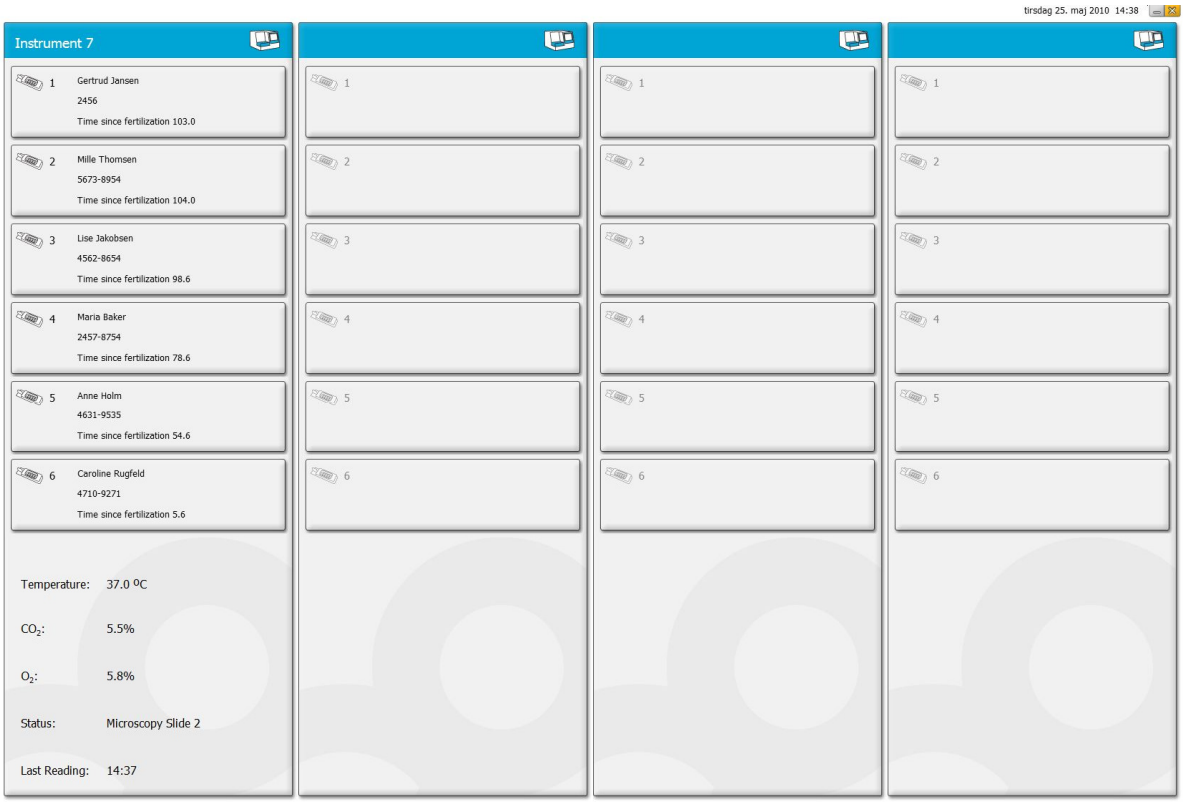
Unisense FertiliTech A/S employees will undertake device setup, installation of software and training of personnel involved in the routine workflow using the device. Unisense FertiliTech A/S will perform maintenance and software update to ensure efficient use of the EmbryoViewer™ workstation. Training and instruction of personnel will be performed by Unisense FertiliTech A/S employees coincident with installation of EmbryoScope™ and/or EmbryoViewer™.

4 Running



In this part of the EmbryoViewer™ it is possible to inspect running slides in EmbryoScopes™ connected to the EmbryoViewer™ workstation.

4.1 View running


tirsdag 25. maj 2010 14:38
Instrument 7
1 Gertrud Jansen 2456 Time since fertilization 103.0
2 Mille Thomsen 5673-8954 Time since fertilization 104.0
3 Lise Jakobsen 4562-8654 Time since fertilization 98.6
4 Maria Baker 2457-8754 Time since fertilization 78.6
5 Anne Holm 4631-9535 Time since fertilization 54.6
6 Caroline Rugfeld 4710-9271 Time since fertilization 5.6
Temperature: 37.0 °C
CO2: 5.5%
O2: 5.8%
Status: Microscopy Slide 2
Last Reading: 14:37

This page shows all running slides from all EmbryoScopes™ connected to the EmbryoViewer™.

- Shows up to 4 connected EmbryoScopes™
- Shows up to 6 running slides from each of the connected EmbryoScopes™
- For each slide, patient name, patient ID and time since fertilization are shown
- For each connected EmbryoScope™ the current incubation condition are shown (incubation temperature and gas concentrations)
- Status of the EmbryoScope™
- Time for last reading of data from the EmbryoScope™

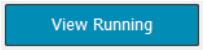
4.1.1 Running slides

Click on one of the running slides

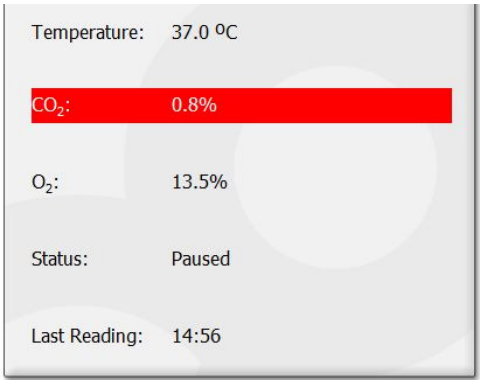
and the corresponding slide overview is shown. Note that running slides are not shown in the database overview pages "View All Slides" and "Instrument", as these slides are not completed. When a slide is ended in the EmbryoScope™, all the data related to this slide will appear in the database overview.

4.1.2 Alarm status

If an alarm occurs in the EmbryoScope™ the title bar will be coloured red.

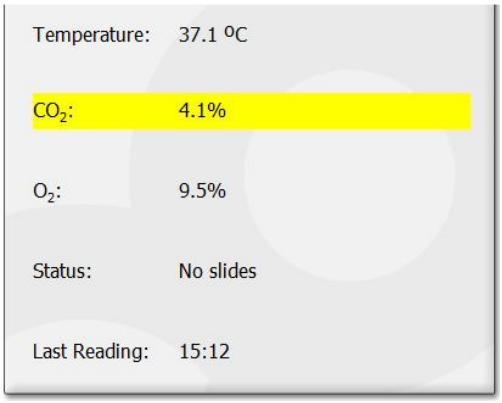
To check the alarm type click 

. Below the slide boxes a red bar indicates whether it is a temperature, CO_2, O_2 alarm or an alarm indicating that the connection between the EmbryoScope™ and the EmbryoViewer™ is lost (time for last reading alarm).



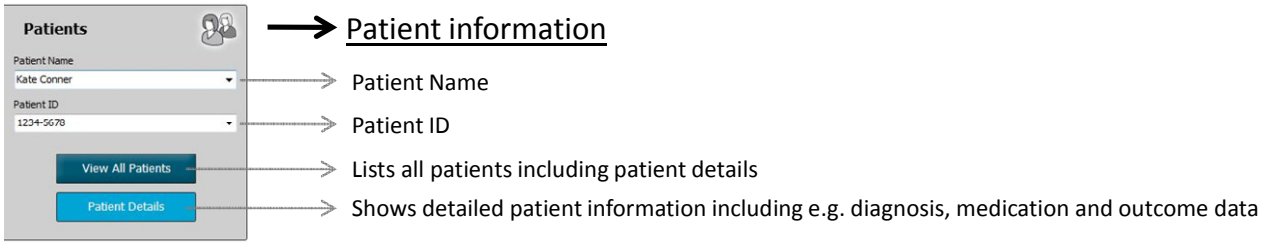
For detailed information on how to handle the alarm on the EmbryoScope™, consult the EmbryoScope™ user manual.

When the alarm in the EmbryoScope™ stops, (because the parameter causing the alarm is back within accepted range) the red alarm bar, both on the title bar and on the specific parameter, changes to yellow to indicate that an alarm has occurred.



When the alarm has been reset on the EmbryoScope™ the colour on the title bar and on the specific parameter changes from yellow to grey.

5 Patients



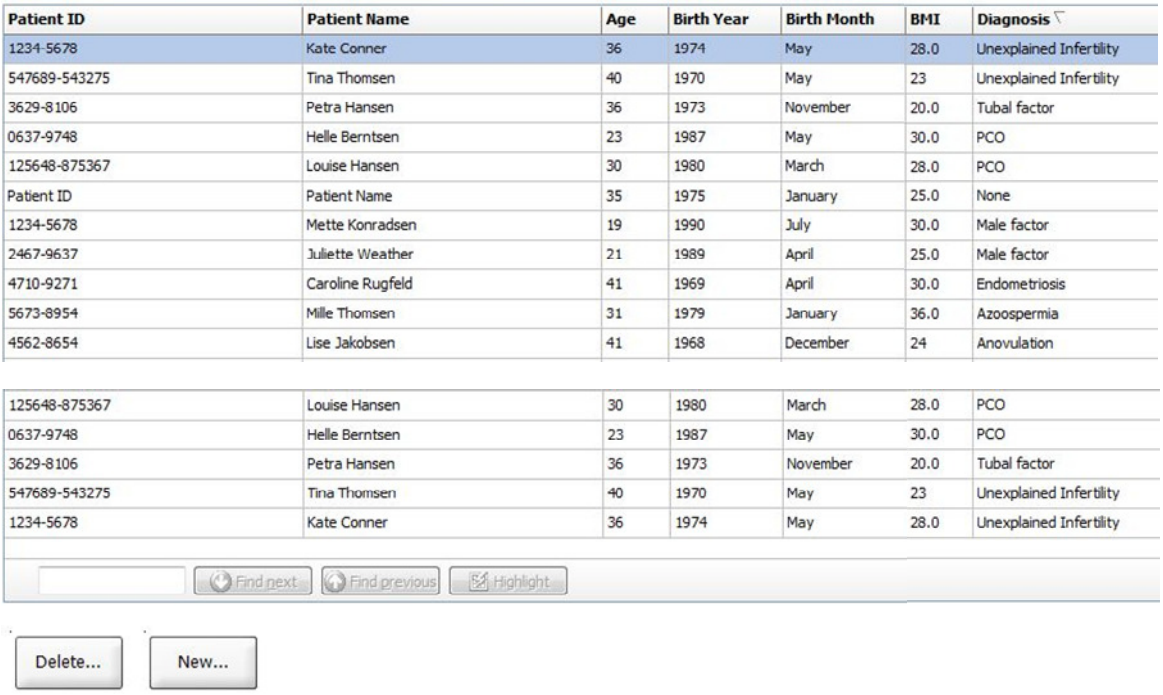
This part of the EmbryoViewer™ allows the user to navigate through patient and treatment details. The navigation panel shows patient name and patient ID of highlighted slide in the patient overview.

NOTE: Patient information
• The clinic shall be solely responsible for ensuring that all local rules and regulations are observed in connection with upload of patient information to Unisense FertiliTech A/S and that patients are informed about such upload of data. • Only anonymous patient information may be uploaded to Unisense FertiliTech A/S. PATIENT ID MAY ONLY BE UPLOADED IF THE ID NUMBER IS AN INTERNAL NUMBER USED BY THE FERTILITY CLINIC. If the patient ID is a social security number or any other traceable personal ID number it may NOT be uploaded to Unisense FertiliTech A/S

5.1 View all patients

This page lists all patients in the database. The information listed is

- Patient ID and name
- Age
- Birth year and month
- Body mass index (BMI)
- Diagnosis
- Comments regarding the patient



Patient ID	Patient Name	Age	Birth Year	Birth Month	BMI	Diagnosis
1234-5678	Kate Conner	36	1974	May	28.0	Unexplained Infertility
547689-543275	Tina Thomsen	40	1970	May	23	Unexplained Infertility
3629-8106	Petra Hansen	36	1973	November	20.0	Tubal factor
0637-9748	Helle Berntsen	23	1987	May	30.0	PCO
125648-875367	Louise Hansen	30	1980	March	28.0	PCO
Patient ID	Patient Name	35	1975	January	25.0	None
1234-5678	Mette Konradsen	19	1990	July	30.0	Male factor
2467-9637	Juliette Weather	21	1989	April	25.0	Male factor
4710-9271	Caroline Rugfeld	41	1969	April	30.0	Endometriosis
5673-8954	Mille Thomsen	31	1979	January	36.0	Azoospermia
4562-8654	Lise Jakobsen	41	1968	December	24	Anovulation

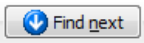
125648-875367	Louise Hansen	30	1980	March	28.0	PCO
0637-9748	Helle Berntsen	23	1987	May	30.0	PCO
3629-8106	Petra Hansen	36	1973	November	20.0	Tubal factor
547689-543275	Tina Thomsen	40	1970	May	23	Unexplained Infertility
1234-5678	Kate Conner	36	1974	May	28.0	Unexplained Infertility

The data can be sorted by clicking on the header row for each column. Double clicking on a patient row activates the

page.

5.1.1 Searching a patient name or ID

Below the patient table there is a search space

where it is possible to search for a name or number, or alternatively part of it. Clicking 

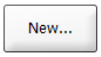
or

, moves the blue highlight bar in the table to the next or previous row containing the name or number. Clicking

, highlights the searched name or number in the table in blue.

5.1.2 Create or delete a patient

Click

, deletes all the data related to the highlighted patient. Click 

creates a new patient, which can be linked to a slide or treatment ID.

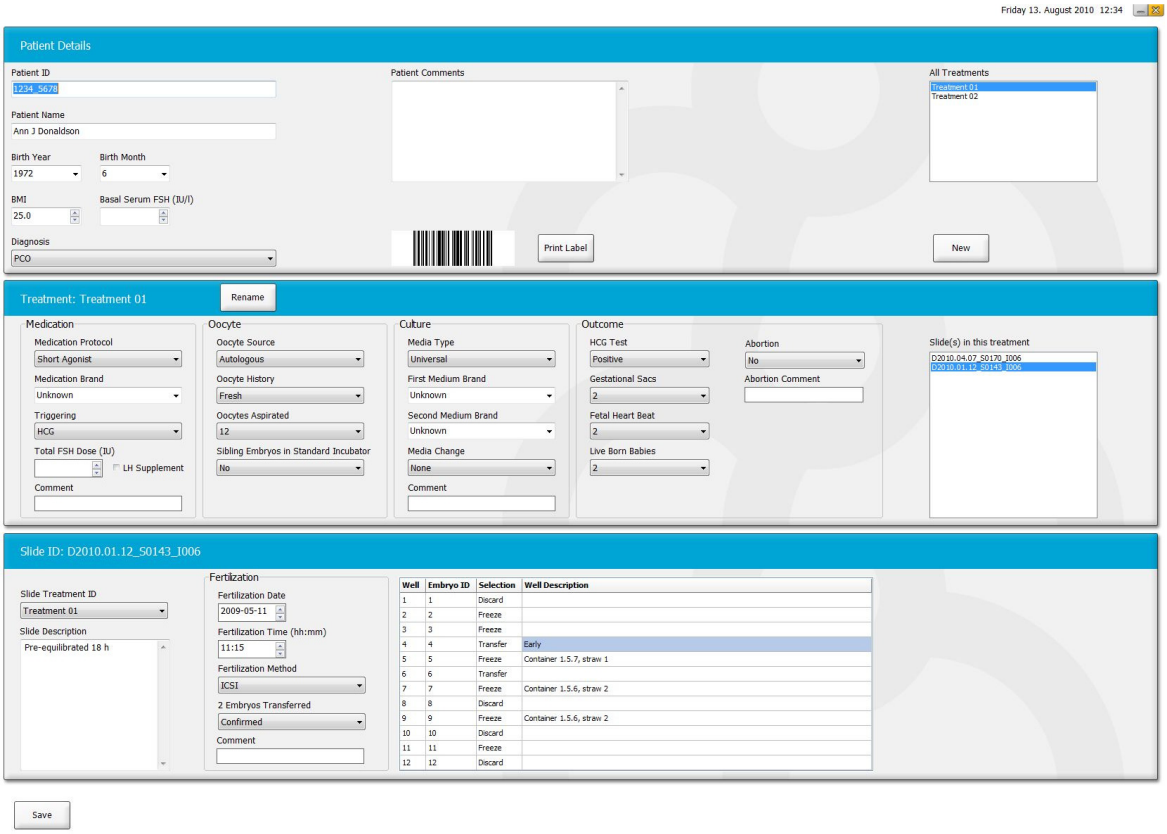
A new patient can be created on this page before loading slides in the EmbryoScope™ and then slide-labels with patient ID and patient name can be printed for the slide(s). When the slide(s) associated to the patient is created on the EmbryoScope™, the EmbryoScope™ shows a list in a drop down menu of patient name's and patient ID's that have previously been created in either the EmbryoScope™ or the EmbryoViewer™. For coupling of treatment ID with slide ID see section 5.2.11.

NOTE: It is essential that the correct patient ID is chosen on the EmbryoScope™ if a new slide is added to an existing patient.

5.2 Patient details

This part of the EmbryoViewer™ provides the user with patient information, treatment and slide information.

5.2.1 Detailed patient and treatment information



This page shows three boxes, the top box where patient information can be specified or is loaded via connection to the EmbryoScope™, the middle box where treatment information and outcome data can be specified, and the bottom box where slide information is shown.

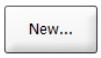
5.2.2 Patient details

Information in the patient details box is:

- Patient ID and name
- Birth year and month

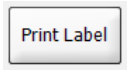
- Body mass index (BMI)
- Basal serum FSH
- Patient diagnosis
- Comments related to the patient

All treatments associated with the patient are listed in the panel on the right side of the "Patient Details" box. The highlighted treatment is the treatment shown in the middle box. Clicking on different treatments in the "All Treatments" panel switches the middle box between the different treatments.

Click 

creates a new treatment, which can be linked to a slide using the bottom slide box, see section 5.2.11.

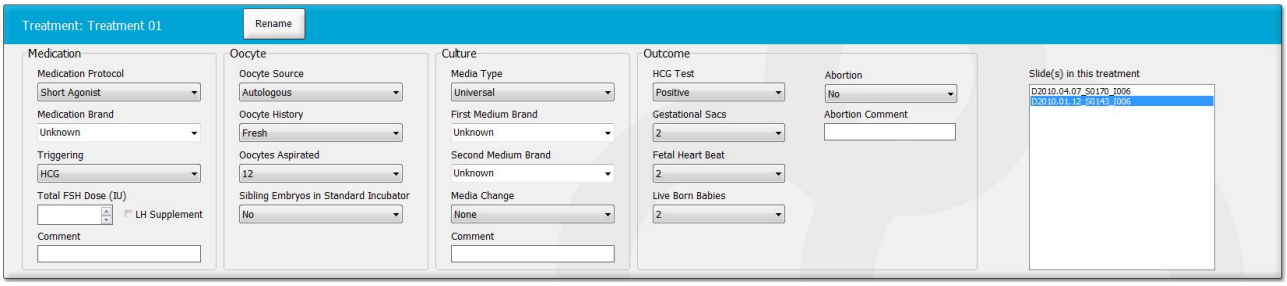
5.2.3 Printing slide-label

Click 

prints a slide-label with a barcode and patient name and patient ID. In order to print the slide-label before the slide is started on the EmbryoScope™ the patient needs to be created on the "View All Patients" page, see section 5.1.2. If the patient ID is too long for the barcode a warning message is shown instead of a barcode.

5.2.4 Treatment information

In the treatment box (middle box), detailed information about the treatment can be specified. The blue header bar shows the treatment name. All new treatments are named "Unknown" until renamed by user. The grey drop down boxes has predefined values, whereas the white drop down boxes is editable and the user can write in information. Values previously written in the white drop down boxes are shown to make input faster.



5.2.5 Medication

In this box information related to the medication used in the patient treatment are typed in, i.e. medication protocol, medication brand, type of triggering, total FSH dose, checkbox for indicating LH supplement and a comment space related to medication.

5.2.6 Oocyte information

In this box information related to the oocyte are typed in, i.e. oocyte source (autologous, donor, other), oocyte history (fresh, thawed, other) and number of oocytes aspirated. If there are embryos from the same treatment that is incubated in a standard incubator the information should be specified in the "sibling embryos in standard incubator" box.

5.2.7 Culture conditions

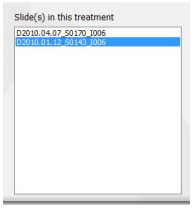
In this box information on the embryos culture conditions are typed in i.e. media type, brand of the first and second media, whether a media change are performed and a comment space related to culture conditions.

5.2.8 Outcome

In this box the outcome data is typed in, result of the HCG test, number of gestational sacs, number of fetal heart beats observed, number of live born babies, information of abortion and a comment space related to abortion e.g. the type of abortion can be written in the comment space.

5.2.9 Multiple slides with a treatment

All slides associated to this treatment are listed in a panel in the right side of the treatment box.

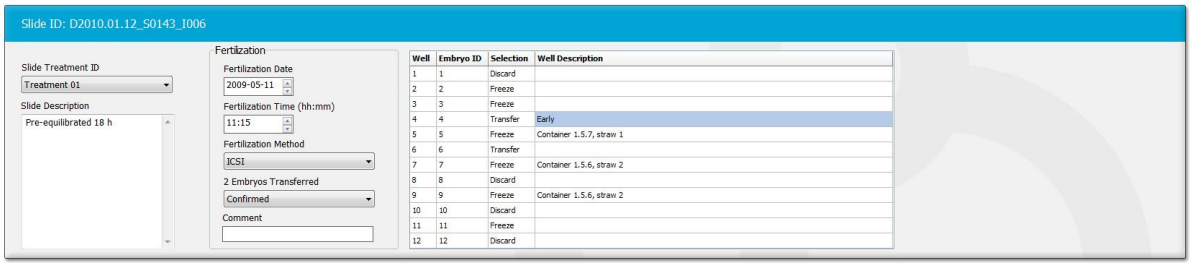


The blue highlighted slide is the slide shown in the bottom box. Clicking on different slides in the "Slide(s) with this treatment" panel switches between the slides shown in the bottom box.

NOTE: It is essential that the correct patient ID is chosen on the EmbryoScope™ if a new slide is added to an existing patient.

5.2.10 Slide information

In the bottom slide box information related to the specific slide are shown, and it is possible to associate or move slides between different treatments. Information from the EmbryoScope™ on fertilization date and time are shown. Fertilization method and a comment can be added. In the right side of the slide box a panel listing embryo specific information (Embryo ID, selection and description) from the EmbryoScope™ is shown.



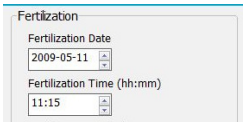
5.2.11 Linking slide and treatment

In the slide box a slide can be linked to an existing treatment using the "Slide Treatment ID" drop down menu.

NOTE: It is essential that the correct patient ID is chosen on the EmbryoScope™ if a new slide is added to an existing patient or treatment.

5.2.12 Changing fertilization time

Fertilization date and time can be manually changed after the slide is ended on the EmbryoScope™.



NOTE: changing fertilization date and time and clicking "Save" overwrites the original fertilization date and time from the EmbryoScope™. The original fertilization date and time can only be restored by importing the raw data from the EmbryoScope™ again.

5.2.13 Embryo specific information

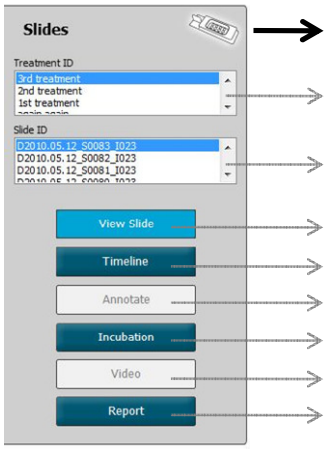
Information related to specific embryos (embryo ID and description) can be written when adding a slide on the EmbryoScope™, and this information is listed in the panel. Selecting embryos for transfer, freezing or discard will appear on this list. The "Well Description" space is editable so additional information on specific embryos can be inserted here after a slide is ended. For example information on location of freezing can be written here and will appear on the "Laboratory Data" report page, section 6.6.1.

5.2.14 Save patient details

Click

and save all updated patient information in the patient details and the treatment box.

6 Slides



Slide and embryo details

Treatment ID (if a patient has several treatments, these are shown)

Slide ID (if several slides belong to the same patient, these are shown)

Shows time-lapse films of embryos from the specific slide

Shows embryos from the specific slide in a timeline view

Detailed view of embryos for annotation of e.g. cleavage times

Running conditions for the specific slide e.g. incubation temperature and gas concentration

Exports video sequences and single images

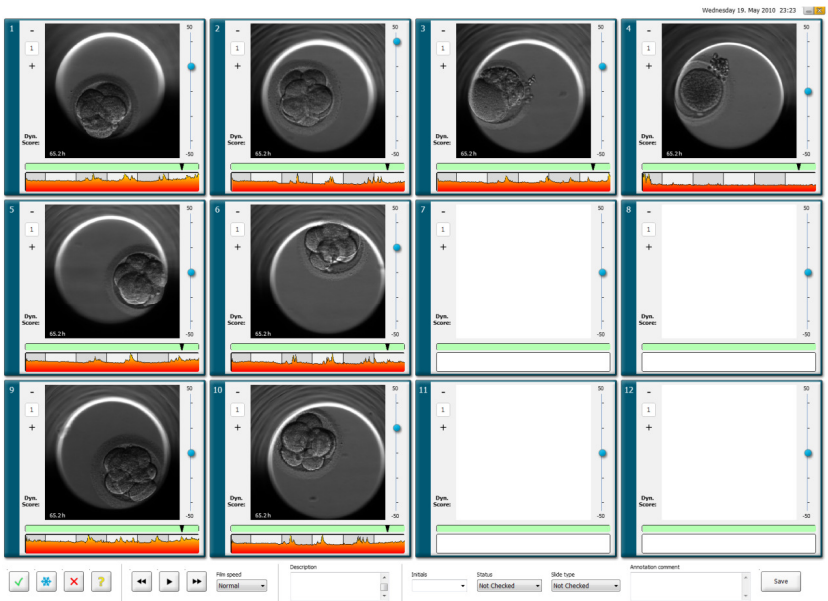
Generates report sheets; laboratory data, instrument data, patient information

This part of the EmbryoViewer™ provides the user with an overview of the embryo time-lapse information.

6.1 View slide

When clicking the

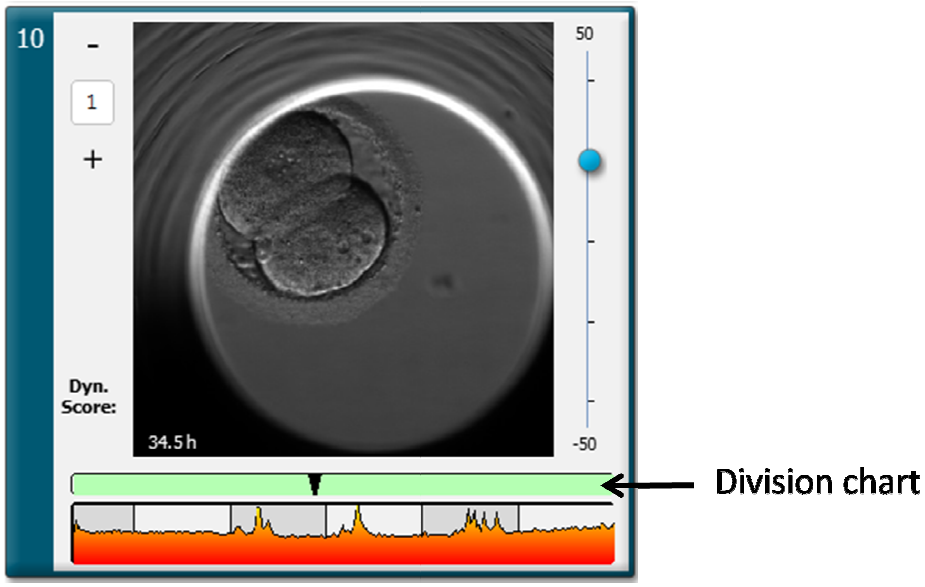
button images of all embryos in the active slide are shown on the screen. The positions of the images on the screen are equivalent to the positions of the embryos in the EmbryoSlide™. The last image of each embryo taken during the incubation is shown.



6.1.1 Time-lapse of embryo development

Viewing time-lapse - scroll wheel

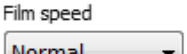
The embryo development can be viewed by turning the scroll wheel (the PowerMate™ with the blue light). Turning the scroll wheel clockwise displays the images of the embryo forwards in time, turning the scroll wheel counter clockwise displays the images backwards in time.



The black triangle shows which position the presently shown image has in the entire film of the embryo development illustrated by the green division chart.

Viewing time-lapse - buttons

Alternatively the time-lapse images can be viewed by using the buttons in the panel at the bottom of the page:

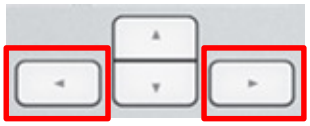
- Clicking displays the previous images in the time-lapse
- Clicking plays the time-lapse film for all embryos on the slide. When pressed again appears and the film pauses
- Clicking displays the next images in the time-lapse series
- Preferred film speed can be chosen in the drop down menu: 

Viewing time-lapse - mouse

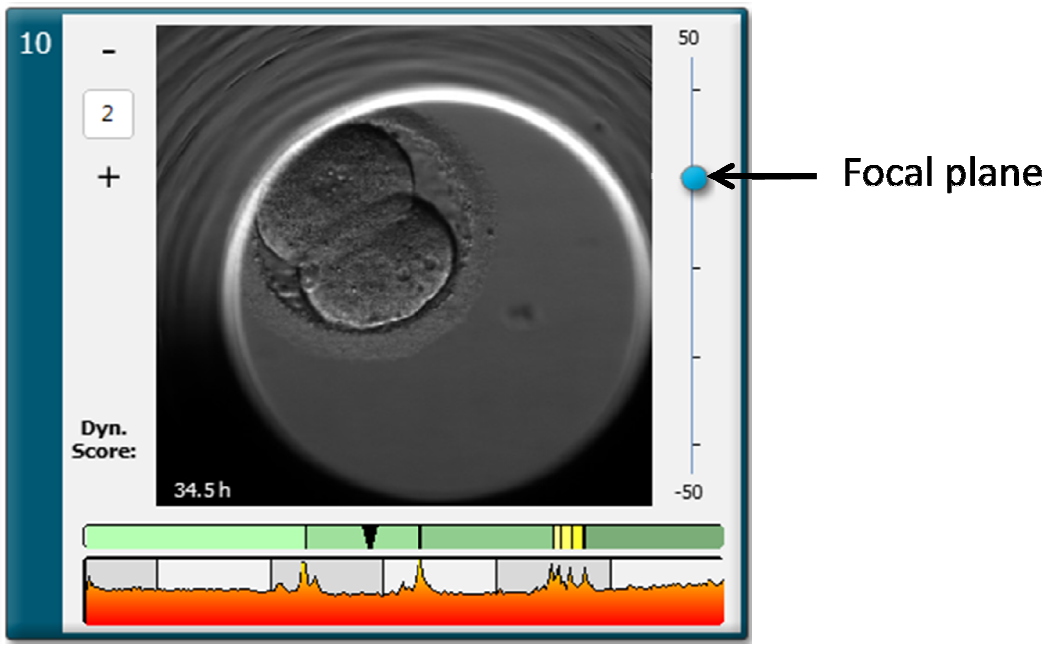
The displayed image can also be changed using the mouse to click on the new desired position in the green bar.

Viewing time-lapse - right and left arrows on the keyboard

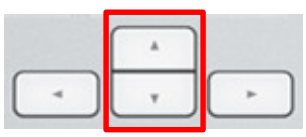
Tapping the right arrow steps the time-lapse forwards, left arrow steps the time-lapse backwards.



6.1.2 Different focal planes

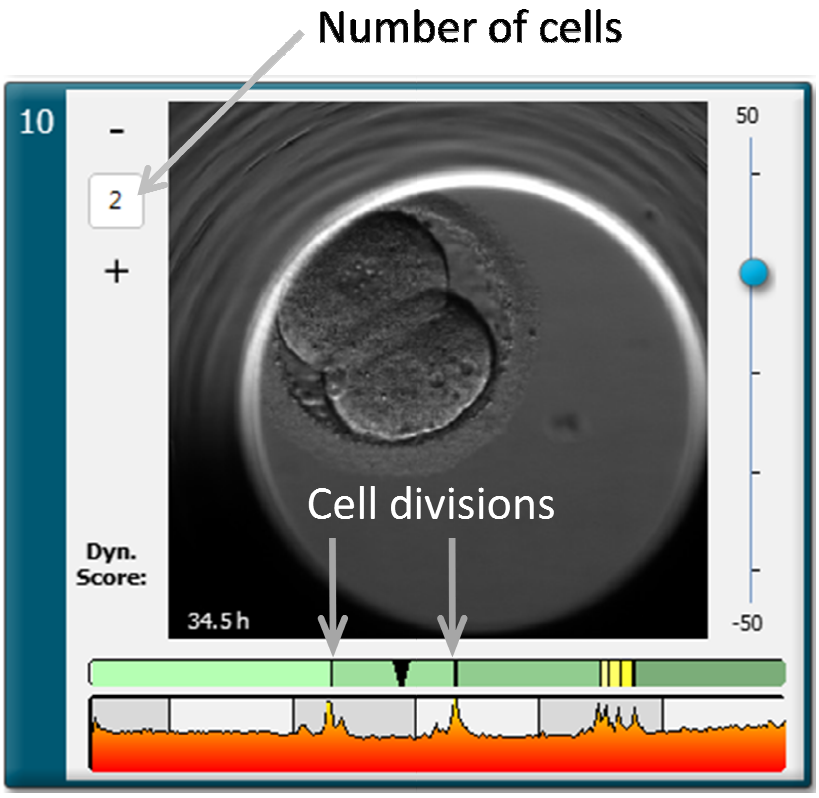


Images are taken in different focal planes. To the right of the image a bar with tick marks indicates this stack of images. The blue dot indicates the focal plane of the shown image. By moving the blue dot up and down the relevant image will be displayed. Just clicking above (or below) the dot displays the image plane just above (or below) the presently shown. If the cursor is placed over the image, arrow up (or down) moves the focal plane up or down, respectively. The scroll wheel on the mouse can also be used to scroll up or down through the images from different planes.



6.1.3 Cell divisions

When a cell division is observed it can be annotated by clicking the plus or minus signs above and below the white space in the upper left corner of the box until the relevant number of cells are displayed. A black vertical line appears in the division chart to indicate the cell division.



Alternatively the annotation can be done by clicking on the white space, which opens a drop down menu with the following options:

1, 2, 3, 4, 5, 6, 7, 8, 9+ for the number of cells

M (morula), B (blastocyst), EB (expanded blastocyst), HB (hatching blastocyst) for further development and Dead for atretic embryos.

The color code on the division chart is:

- Green: 1, 2, 4, 8 cells.
- Yellow: 3,5,6,7 cells.
- Blue: M, B, EB, HB.
- Red: Dead.

A division pattern can look like this:

6.1.4 Blastomere activity

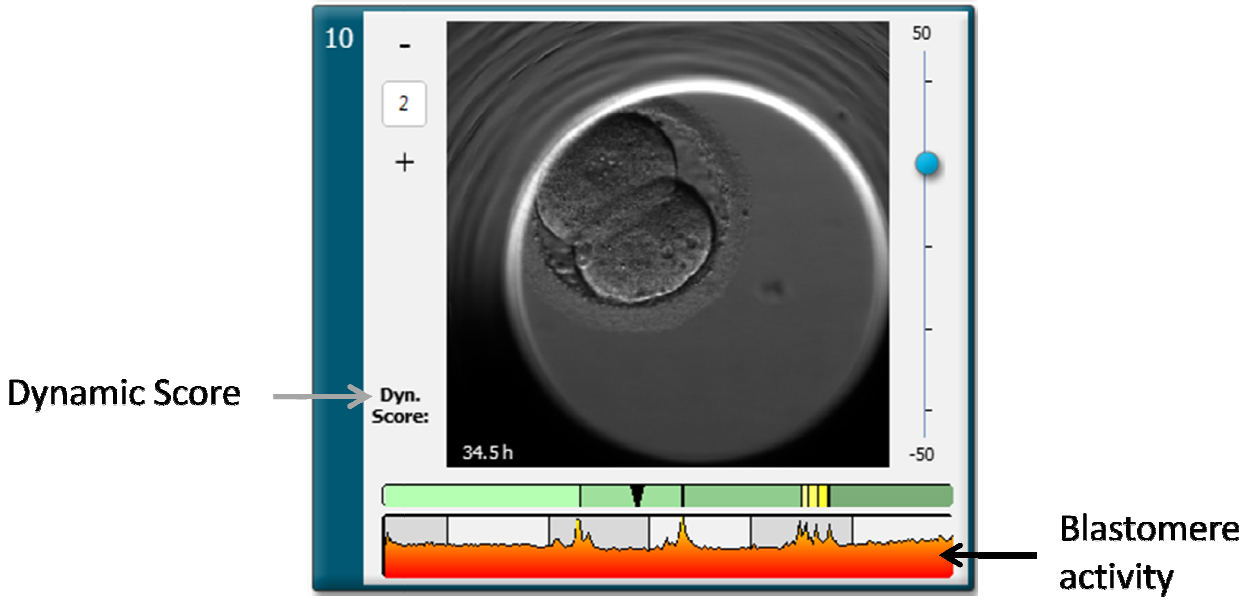


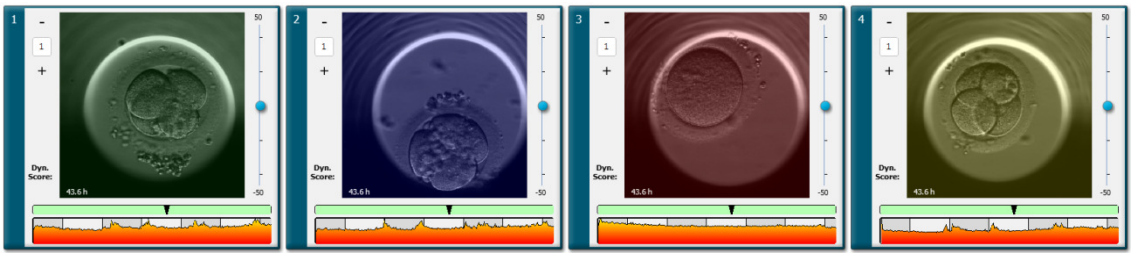
Image series are analyzed automatically in real time with the EmbryoScope™ software. Blastomere activity is a numerical parameter that reflects the amount of movement that has occurred between two consecutive images in the time-lapse image series. The blastomere activity has NO DIAGNOSTIC USE, but can be used to assist the user in identifying periods in the time series where events of interest may be occurring. Peaks in the blastomere activity often occur when cell divisions take place, since the cell divisions lead to movement in the image. An example is given in the image above.

There can be other causes for peaks in the blastomere activity than cell divisions.

6.1.5 Dynamic score

The “Dynamic Score” abbreviated “Dyn. Score” can be annotated in the “Annotate” sheet and if annotated it is displayed to the left of the image.

6.1.6 Embryo selection buttons

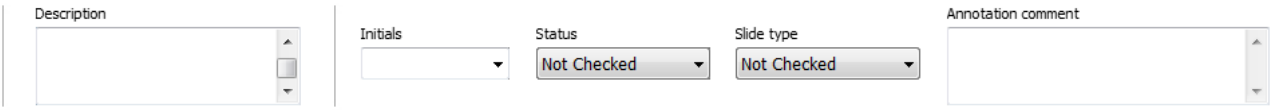


Buttons for marking selected embryos are listed in the panel below the images:

- The button marks embryos selected for transfer. Selected images get a green background
- The button marks embryos selected for freezing. Selected images get a blue background
- The button marks embryos for discarding. Selected images get a red background
- The button marks embryos where decision making is not possible at the time of marking. Selected images get a yellow background

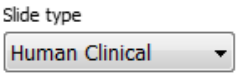
When for example the button is clicked, the icon ( ) is shown to the right of the cursor indicating that the transfer tool is active. One or more embryos for transfer can now be marked by clicking on the images, whereby the images get a green background. Return to normal cursor use is done by clicking on the "Transfer" tool button again. The other three tools work in the same manner.

6.1.7 Annotations regarding the slide



Spaces and drop down menus for slide description, initials of annotating personnel, status of annotation, Slide type and an annotation comment are provided at the bottom of the screen.

6.1.8 Slide type



The drop down menu for slide type has the following options:

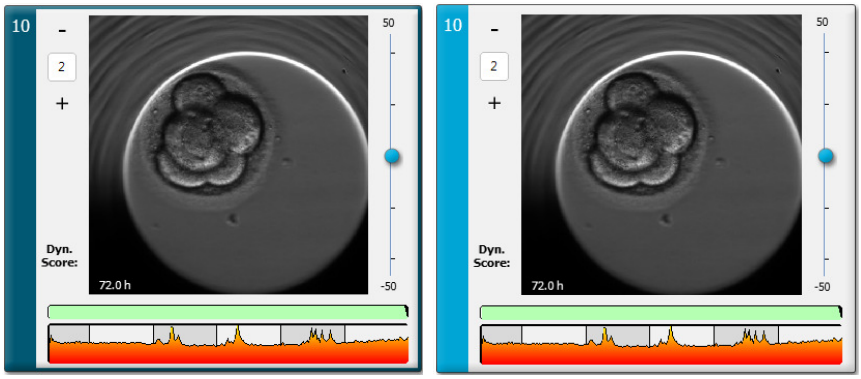
- Human clinical
- Human test
- Animal test
- Other test
- Not checked.

6.1.9 Saving changes

Click the

button to save all updated information on the “View Slide” page. If an attempt is made to update or leave the page before saving, a dialog box will appear asking whether or not the user wants to save the changes before proceeding.

6.1.10 Selecting embryos for annotation



An embryo can be selected by clicking on the image on the slide. The dark blue bar to the left will be highlighted in a light blue colour. One, two or three images can be selected and subsequently displayed on the “Annotation” page.

6.1.11 Shortcut

Double clicking on one of the embryo images opens the “Annotation” sheet with the chosen embryo.

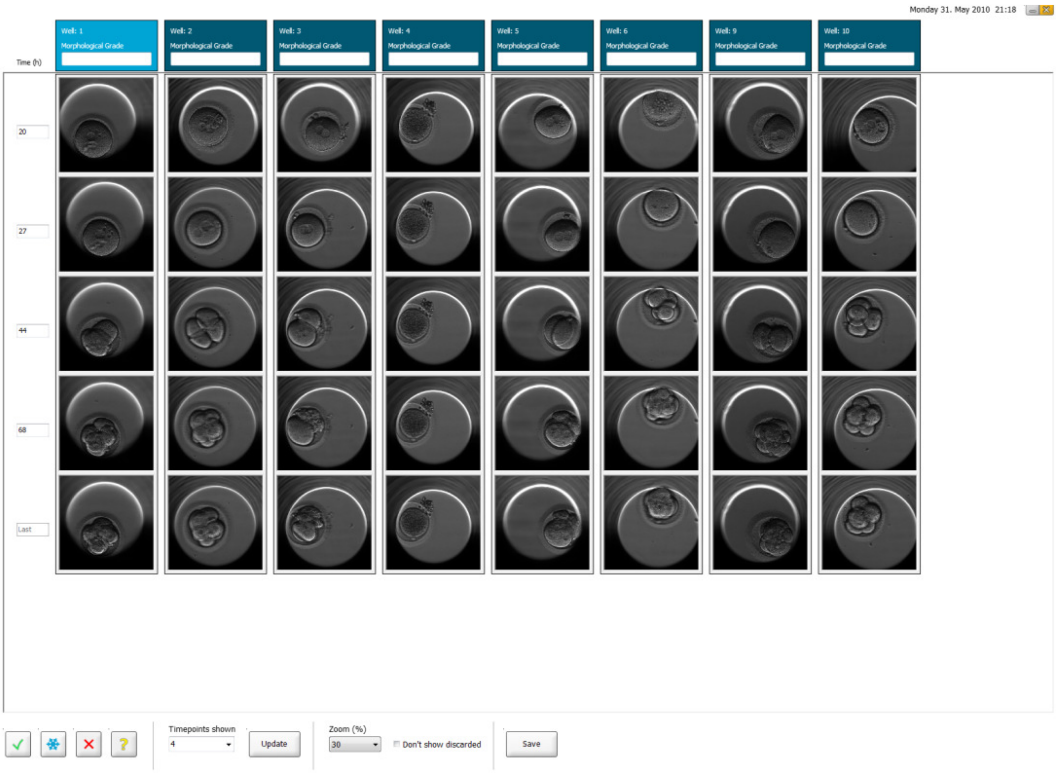
6.2 Timeline

When clicking the

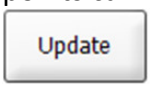
button the embryos within the specific slide are shown at pre-specified time points.

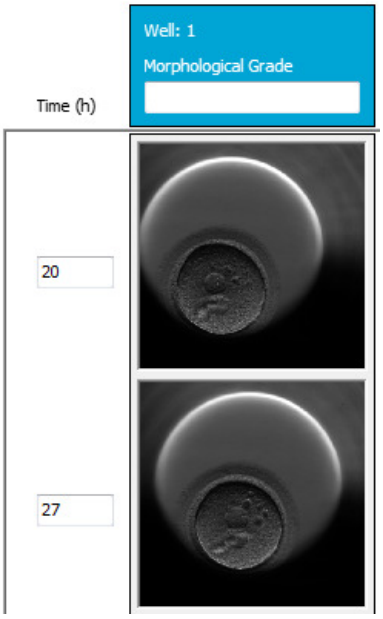
The page gives a fast overview of the embryos in the slide. Embryos that should be discarded can be selected and not be shown on the page, leaving more space for the prevailing embryos that can be selected for transfer, freeze or further observation.

In addition, it is possible to magnify the small images in the “Timeline”.



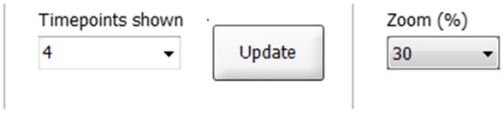
6.2.1 Choosing displayed time points

Preferred time points can be written in the white spaces to the left of the embryo images. When clicking on the  button at the bottom of the page, images of the embryos are displayed at the selected time points. Time points do not need to be written chronologically, as the update function will order them chronologically.

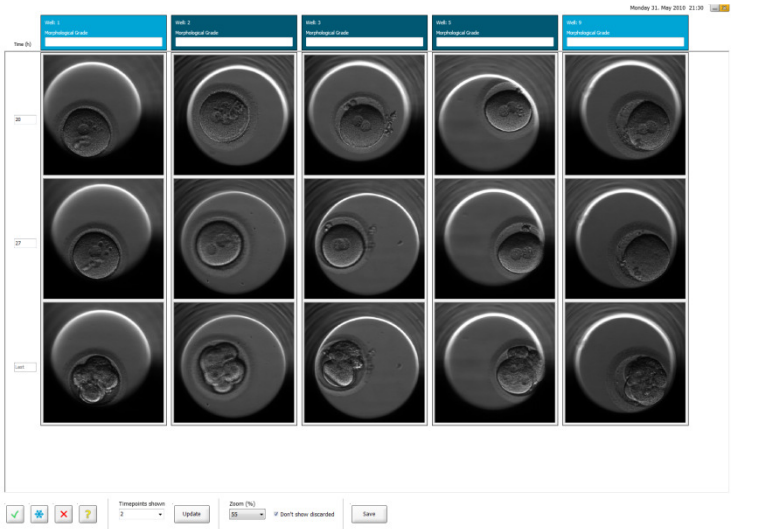


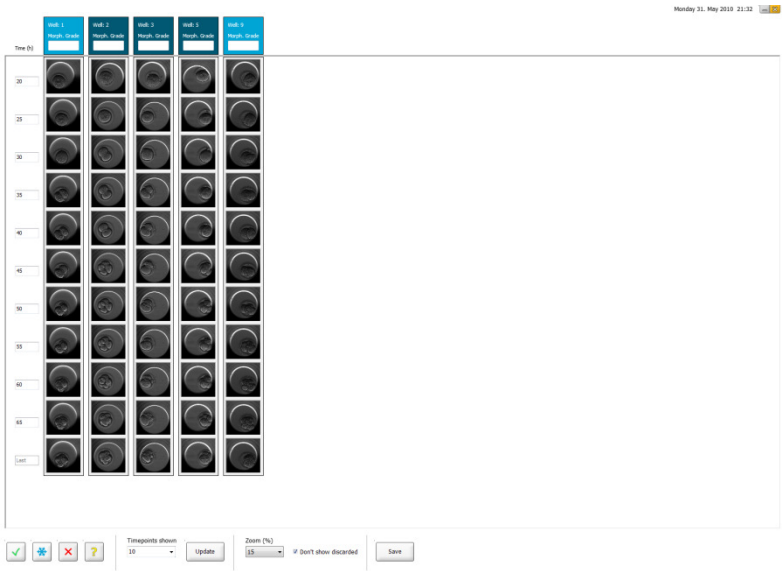
6.2.2 Number of time points shown and zoom level

The number of time points shown can be changed in the "Time points shown" drop down menu at the bottom of the page. Up to 10 time points can be chosen and will be displayed after clicking the update button.



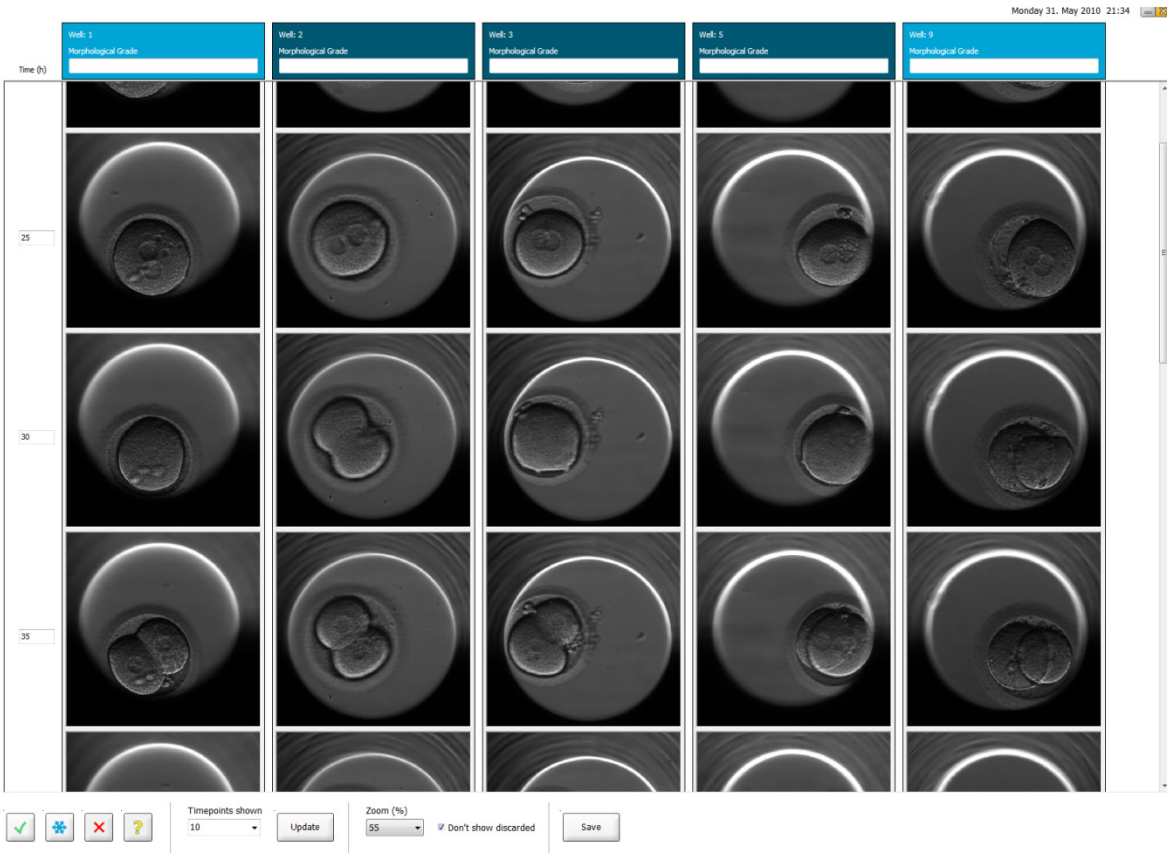
The more time points chosen, the smaller the displayed images, since the space on the screen is limited.





The zoom level can be changed manually on the "Zoom (%)" drop down box. The larger the zoom number, the larger the images displayed.

When more time points and/or embryos are chosen than can be displayed on the page, a scroll bar appears to the right of the images.



6.2.3 Embryo selection in "Timeline"

The four embryo selection buttons for transfer, freeze, discarding and further observation described in section 6.1.6 are also available on the "Timeline" page.

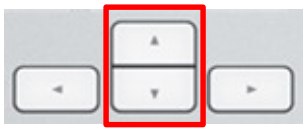
Embryos that should be discarded can be marked with the button, giving the embryos a red background color. If the "Don't show discarded" checkbox is checked, the discarded embryos will no longer be shown on the page. By removing the discarded embryos from the page, more space is available to enlarge the remaining embryos.

If some embryos have been selected for discarding on the "View Slide" page and the "Don't show discarded" checkbox is already checked when opening the "Timeline", the discarded embryos are not shown when the slide is initially opened in "Timeline".

The embryo selections are saved by pressing the Save button. If an attempt is made to update or leave the page before saving, a dialog box will appear asking whether or not the user wants to save the changes before proceeding.

6.2.4 Viewing different focal planes

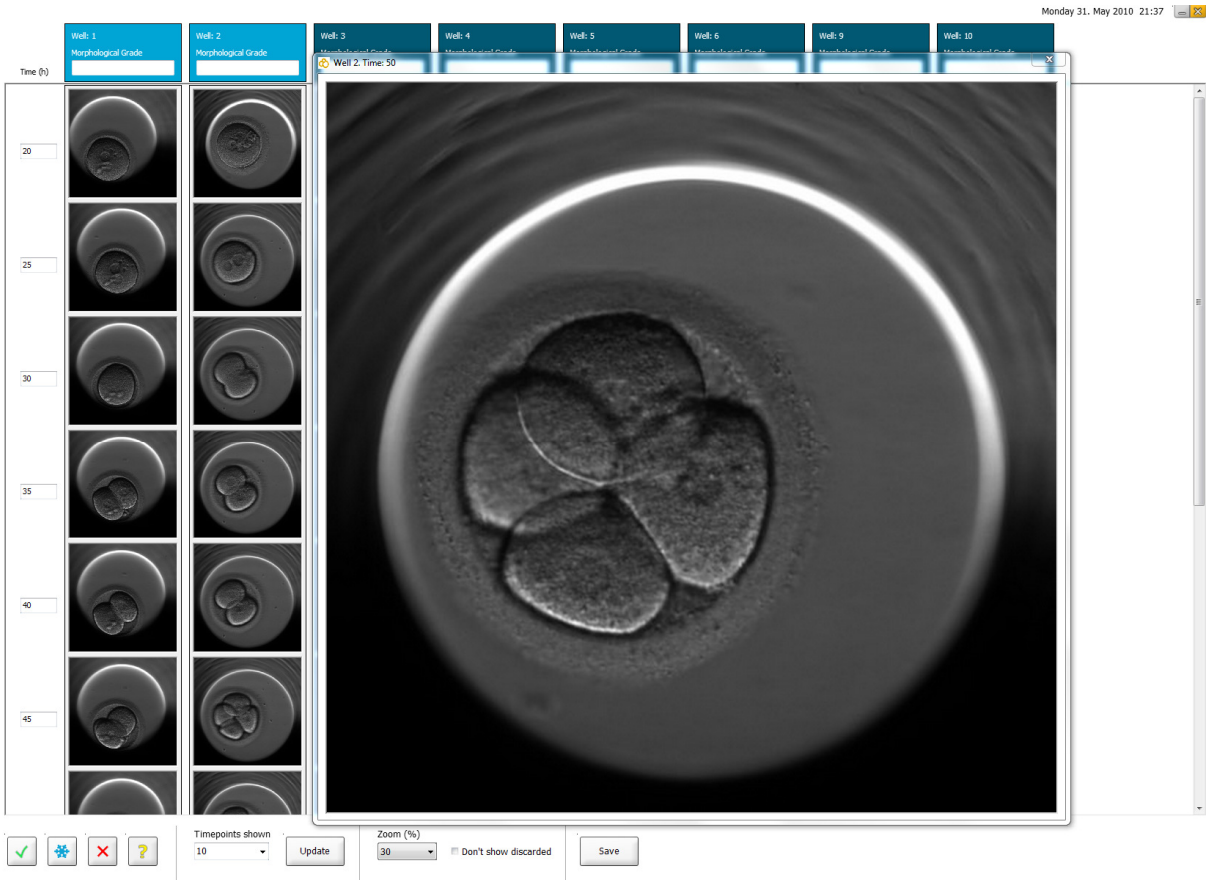
The different focal planes of the image can be viewed by placing the curser over an image (no clicking) and scrolling with the scroll wheel on the mouse or using the up and down arrows on the keyboard.



6.2.5 Magnification of images in "Timeline"

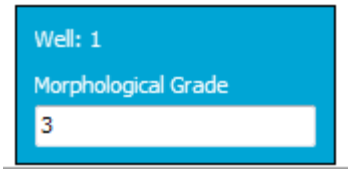
An image can be magnified by double clicking on the image. The image shown in the magnifying frame can be changed to any other image by double clicking on the other image.

In the magnified view the scroll wheel and the up and down arrows can be used to change the focal planes.



6.2.6 Morphological grade

A morphological grade can be given in the box in the header, and will also be displayed in the sheet “Annotate”.



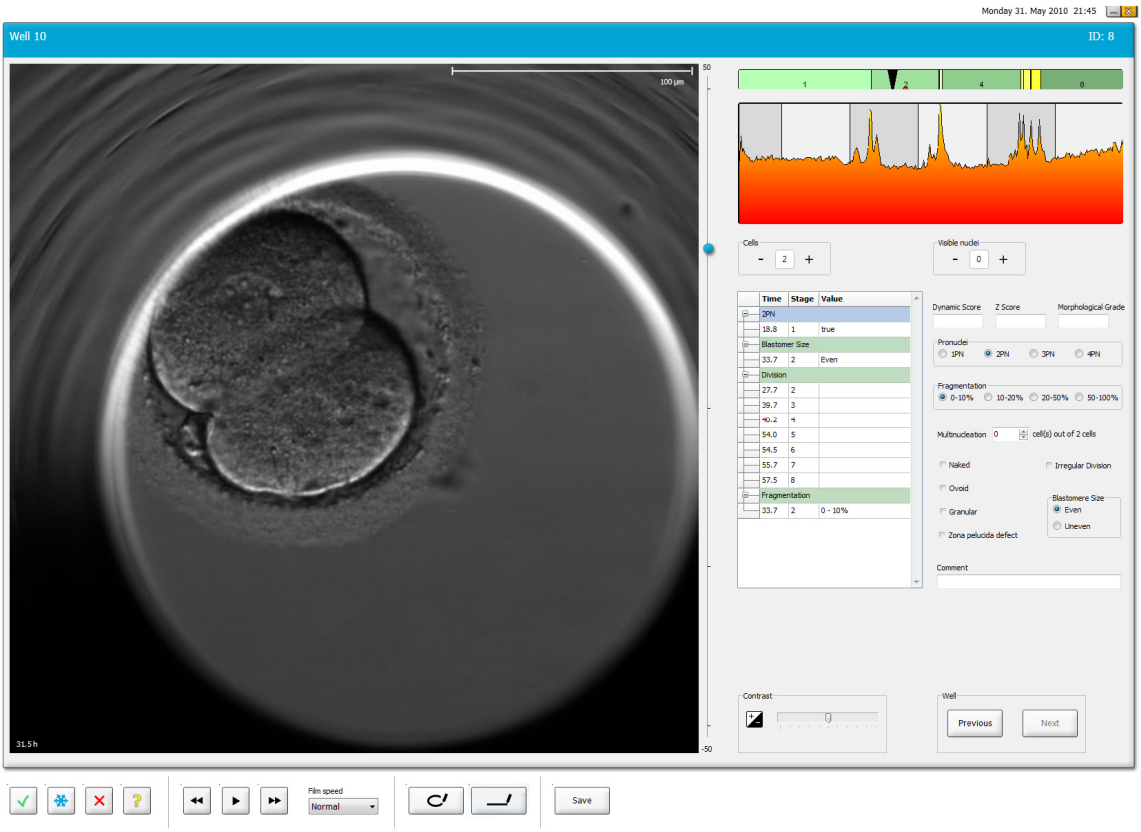
6.2.7 Shortcut

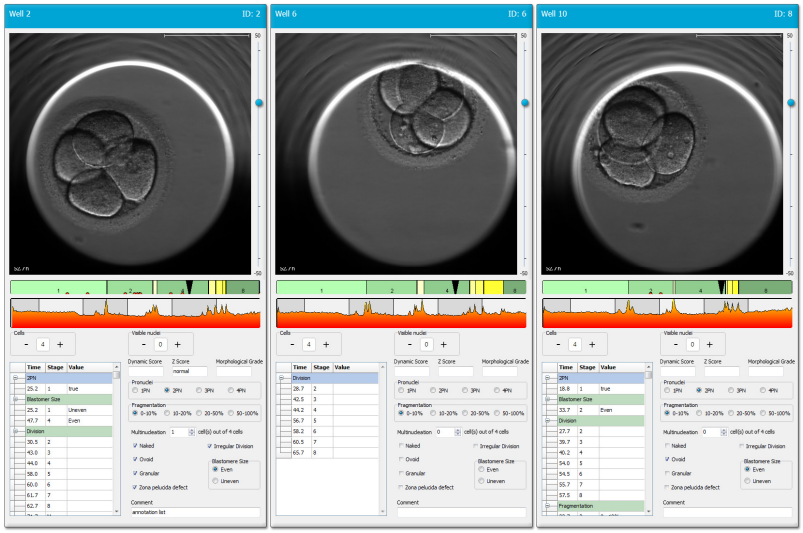
Double clicking on one of the headers of the embryo timelines opens the “Annotation” sheet with the chosen embryo.

6.3 Annotate

The

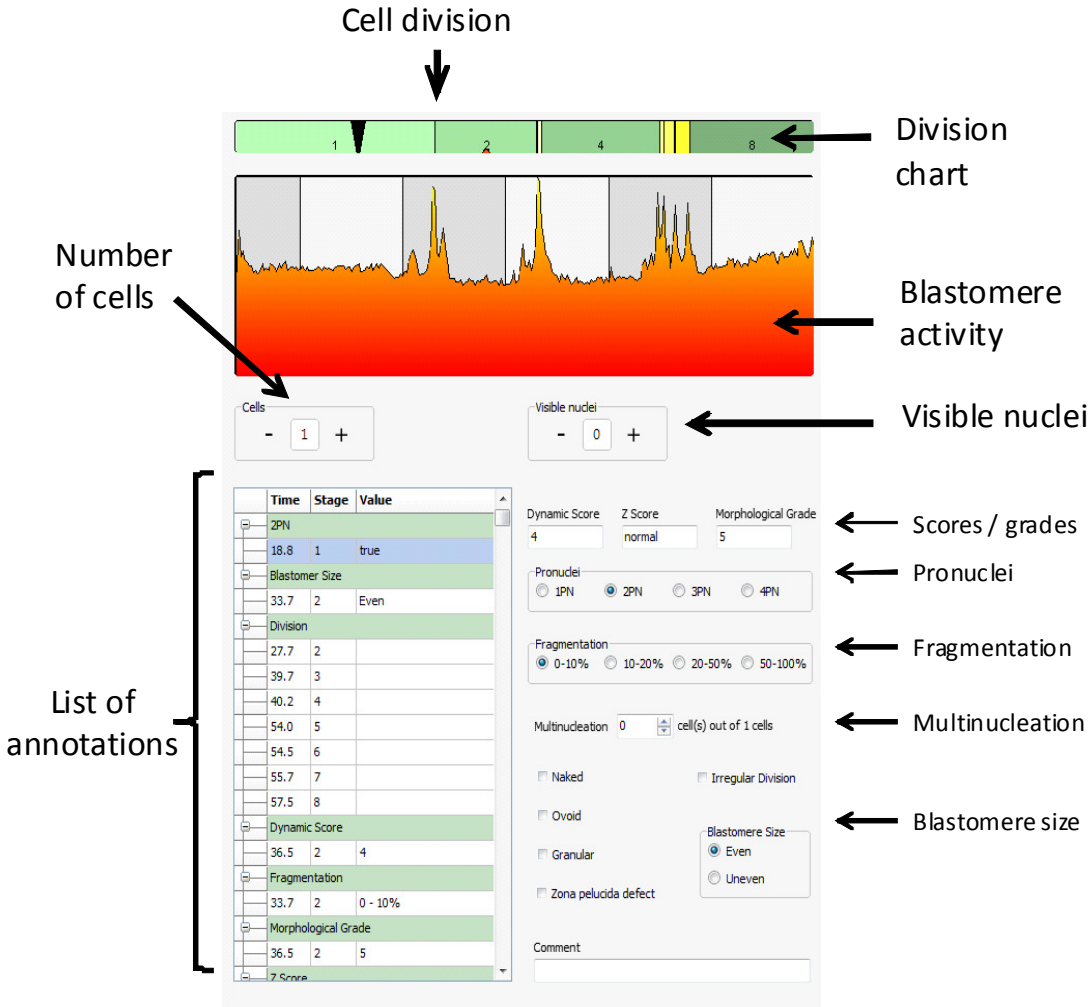
button becomes active when one, two or three embryos have been selected on either the “View Slide” or “Timeline” page. Detailed annotations of the embryos can be done on the “Annotate” page.





6.3.1 Using the annotation table

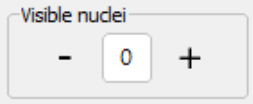
When a specific annotation is done, the time and value are written in the list of annotations. The various annotations are described below:



6.3.2 Cell divisions

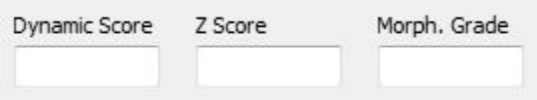
The tool for annotating cell divisions on the division chart works in the same way as the tool on the "View Slide" page (section 6.1.3).

6.3.3 Visible nuclei



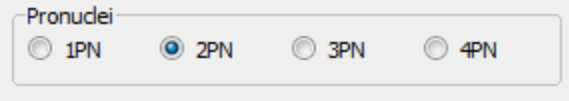
The number of visible nuclei can be annotated, by clicking the plus or minus sign until the number in the box matches the number of visible nuclei on the embryo image. Synchrony or asynchrony in the appearance and disappearance of nuclei can be annotated using this tool.

6.3.4 Dynamic score, Z score, and morphological grade



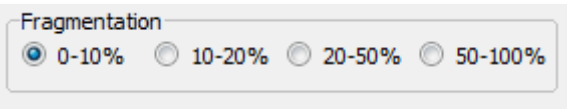
- Dynamic score can be used as an overall score where the time-lapse information has been used in determining the grade
- Z score can be used for grading the pattern of the pronuclei and the pattern of the nuclear precursor bodies in the pronuclei
- Morphological grade can be used as a grade based on the timeline images, the morphological grade can also be assigned on the "Timeline"

6.3.5 Pronuclei



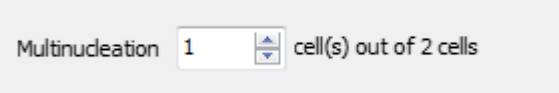
Number of pronuclei before first cell division can be annotated.

6.3.6 Fragmentation



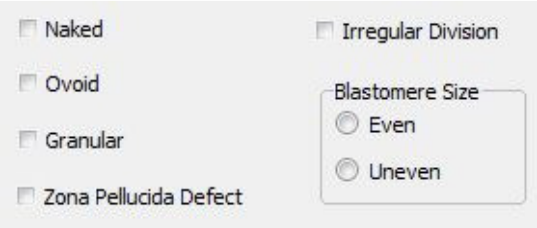
The relative degree of fragmentation of the embryo can be annotated.

6.3.7 Multinucleation



The number of cells in which multinucleation is observed can be annotated.

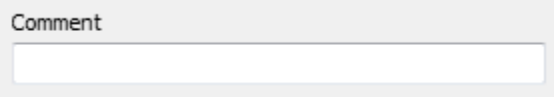
6.3.8 Blastomere size and other properties



The spatial symmetry of the blastomeres can be annotated at for instance the 2, 4, and 8 blastomere stadium.

Various other properties can be annotated by checking the check boxes. The annotations will be shown in the list of annotations and a small red dot is shown at the bottom of the division chart to indicate an annotation.

6.3.9 Comments

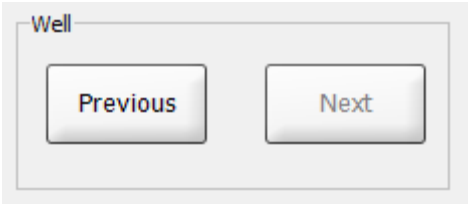


Up to 10 comments can be added to the list of annotations.

6.3.10 Adjusting contrast in the image

Image contrast can be adjusted by sliding the bar. Note this will not change the original images but only they way the images are currently displayed.

6.3.11 Navigate to previous or next well



6.3.12 Embryo selection in "Annotate"

The four embryo selection buttons described in section 6.1.6 are also available in "Annotate".

6.3.13 Time-lapse embryo development in "Annotate"

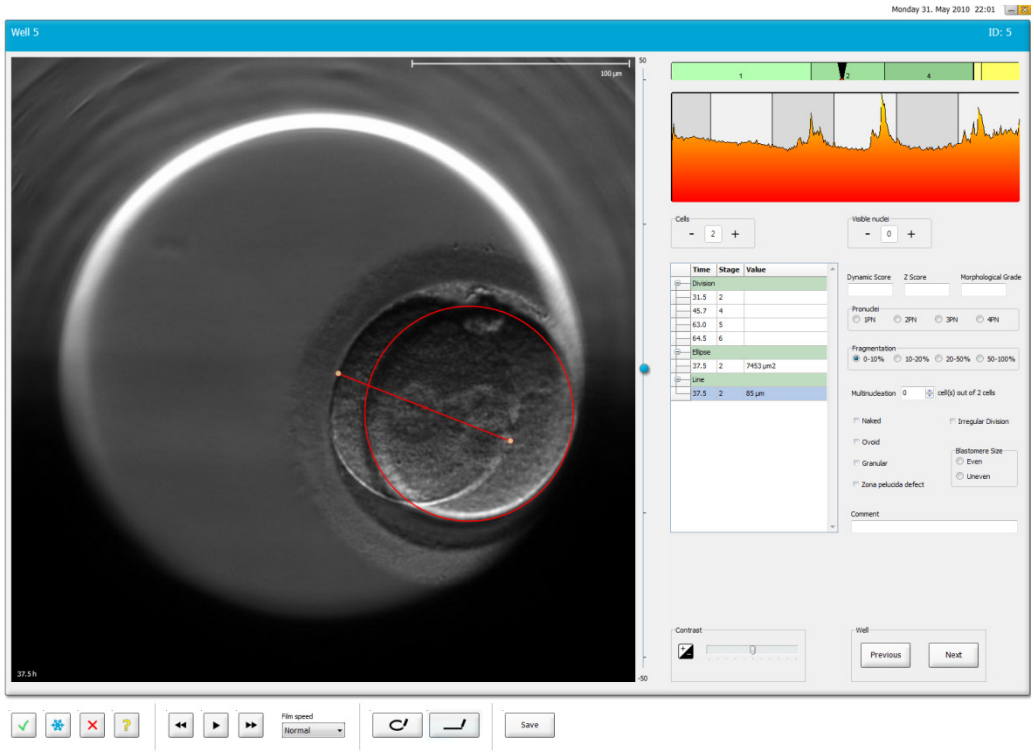
All options for playing the embryo time-lapse film described in section 6.1.1 are available in "Annotate".

6.3.14 Measuring blastomere size

The ellipse tool can be used for estimating the area of a blastomere and/or fragment.

The distance tool can be used for estimating the diameter of a blastomere and/or fragment.

Area and distance are shown in the list of annotations.

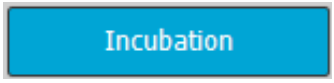


6.3.15 Saving changes

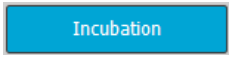
Click the

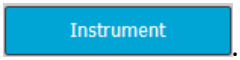
button to save all annotations. If an attempt is made to update or leave the page before saving, a dialog box will appear asking whether or not the user wants to save the changes before proceeding.

6.4 Incubation



6.4.1 Inspection of running conditions

During a run on the Embryoscope™ and/or as a final quality check (QC) it is possible to inspect the running conditions for each EmbryoScope™ instrument. Incubation details can be inspected by clicking 

or finding the slide in the instrument overview table accessed by 

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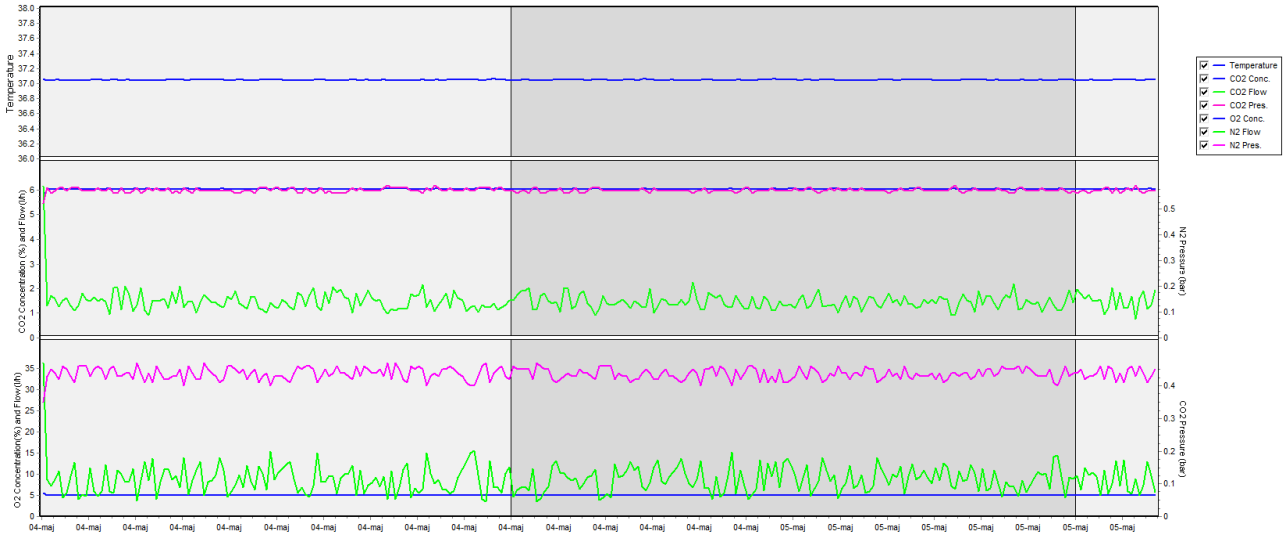
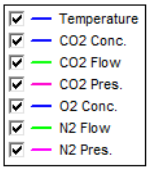
Running conditions for CO_2 and O_2 are only shown if CO_2 and O_2 regulation is chosen on the EmbryoScope™. Running conditions for temperature and gas are shown on graphs. Door openings are indicated by a black cross on the graph.



- Top graph: Incubation temperature (blue)
- Middle graph: CO_2 concentration (blue), flow (green) and pressure (pink)
- Bottom graph: O_2 concentration (blue), flow (green) and pressure (pink)

For all graphs, it is possible to include or exclude the parameters shown on the graph by clicking in the checkbox.



The axis on the graph rescales automatically in accordance with the parameters chosen.

6.4.2 Zoom of graphs

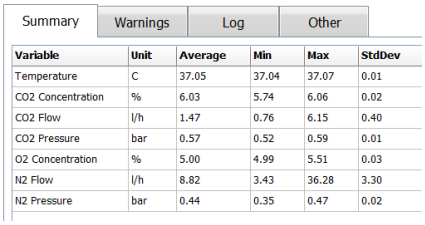
To zoom on a specific part of one of the graphs drag the cursor from left to right, to zoom out drag the cursor in the opposite direction (from right to left).

6.4.3 Detailed running information

Below the graphs detailed information on running conditions for the selected slide are shown in different sheets.

6.4.4 Summary sheet

Running conditions for incubation temperature and gas conditions (average, min, max and standard deviation).



Variable	Unit	Average	Min	Max	StdDev
Temperature	C	37.05	37.04	37.07	0.01
CO2 Concentration	%	6.03	5.74	6.06	0.02
CO2 Flow	l/h	1.47	0.76	6.15	0.40
CO2 Pressure	bar	0.57	0.52	0.59	0.01
O2 Concentration	%	5.00	4.99	5.51	0.03
N2 Flow	l/h	8.82	3.43	36.28	3.30
N2 Pressure	bar	0.44	0.35	0.47	0.02

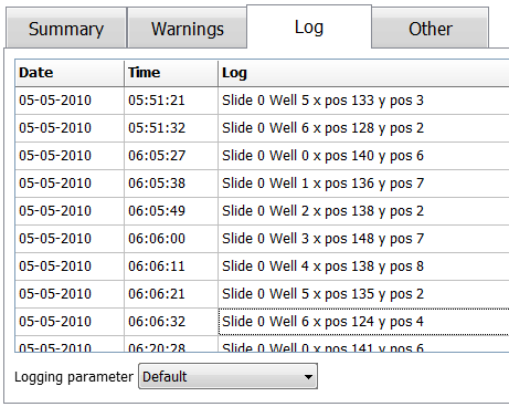
6.4.5 Warnings sheet

The warning sheet lists for example, incubator warnings (alarms), lost connection between the EmbryoScope™ and the EmbryoViewer™, door openings.

Date	Time	Warning
05-05-2010	07:43:24	Door closed
05-05-2010	07:43:27	Door opened

6.4.6 The log sheet

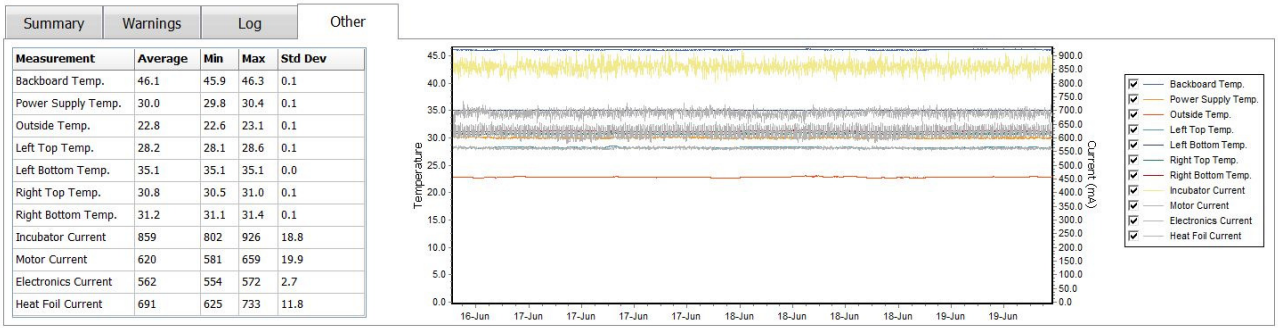
The log sheet lists a number of detailed parameters of instrument functions. There are a number of parameters that are logged during the incubation. The parameters are categorized in the following groups which are available in a drop down menu, 1) Default: Information about timing of slide loading, position of each image, etc. 2) Description: Information about embryo description, slide start/end, program version, etc. 3) Camera: Information about where the best focal plane was found. 4) Incubator settings: O2, CO2 and temperature settings. 5) Instrument parameters: Information about all instrument specific parameters (calibrated during reset). These logs are primarily used for trouble shooting if any problems occur with the EmbryoScope™.



Date	Time	Log
05-05-2010	05:51:21	Slide 0 Well 5 x pos 133 y pos 3
05-05-2010	05:51:32	Slide 0 Well 6 x pos 128 y pos 2
05-05-2010	06:05:27	Slide 0 Well 0 x pos 140 y pos 6
05-05-2010	06:05:38	Slide 0 Well 1 x pos 136 y pos 7
05-05-2010	06:05:49	Slide 0 Well 2 x pos 138 y pos 2
05-05-2010	06:06:00	Slide 0 Well 3 x pos 148 y pos 7
05-05-2010	06:06:11	Slide 0 Well 4 x pos 138 y pos 8
05-05-2010	06:06:21	Slide 0 Well 5 x pos 135 y pos 2
05-05-2010	06:06:32	Slide 0 Well 6 x pos 124 y pos 4
05-05-2010	06:20:28	Slide 0 Well 0 x pos 141 y pos 6

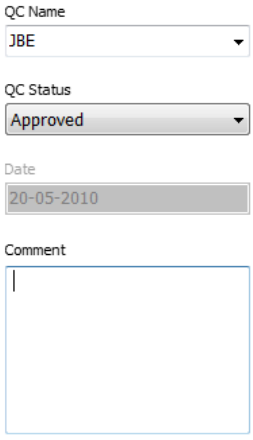
6.4.7 The "Other" sheet

The sheet named "other" lists a table of average, min, max and standard deviations of several running conditions such as temperature within the EmbryoScope™ and current use of different parts of the EmbryoScope™. The parameters are also shown graphically. The parameters can be checked/unchecked in the graph legend. The zoom function also functions in this graph.



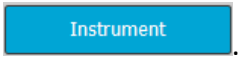
Measurement	Average	Min	Max	Std Dev
Backboard Temp.	46.1	45.9	46.3	0.1
Power Supply Temp.	30.0	29.8	30.4	0.1
Outside Temp.	22.8	22.6	23.1	0.1
Left Top Temp.	28.2	28.1	28.6	0.1
Left Bottom Temp.	35.1	35.1	35.1	0.0
Right Top Temp.	30.8	30.5	31.0	0.1
Right Bottom Temp.	31.2	31.1	31.4	0.1
Incubator Current	859	802	926	18.8
Motor Current	620	581	659	19.9
Electronics Current	562	554	572	2.7
Heat Foil Current	691	625	733	11.8

6.4.8 Save QC status and comments



When quality check of running conditions are performed it is possible to save the name of the person who has performed the QC; the status (approved, disapproved, not checked) and a comment to the QC can be added.

Click

to save this information. The QC status and comments added are also shown on the instrument view page accessed by clicking 

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6.5 Video

The

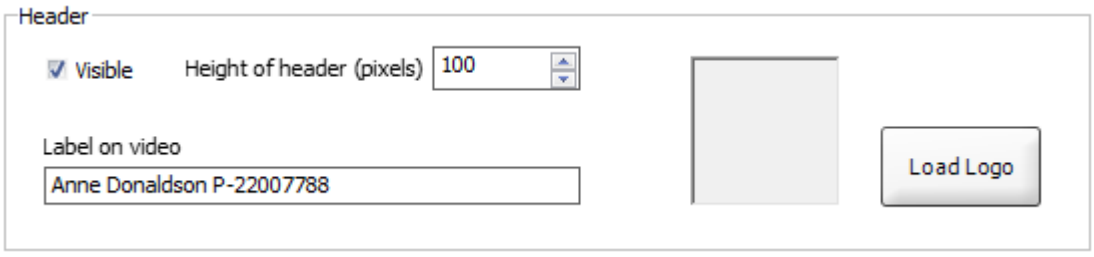
button becomes active when 1-12 embryos have been selected on either the “View Slide” or “Timeline” page.

6.5.1 Generate video of embryo(s)

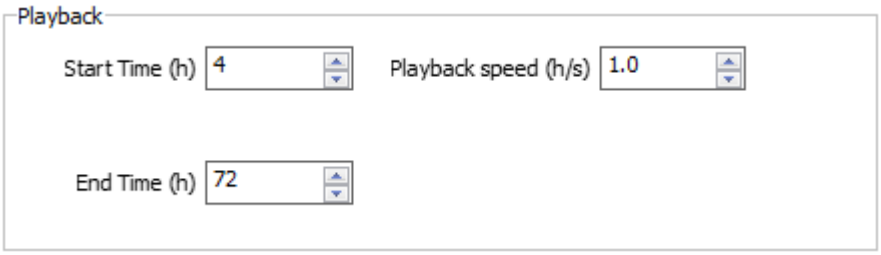
Use the “Video” sheet to specify a range of parameters for the video. The video is generated after pressing the

button.

A header can be placed on the video showing text and the clinic’s logo:



The start and end time as well as the playback speed can be specified in the “Playback” box:

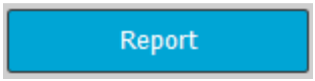


6.5.2 Generate embryo images

Use the "Images" sheet to export the embryo images in jpeg format after clicking the

button.

6.6 Report

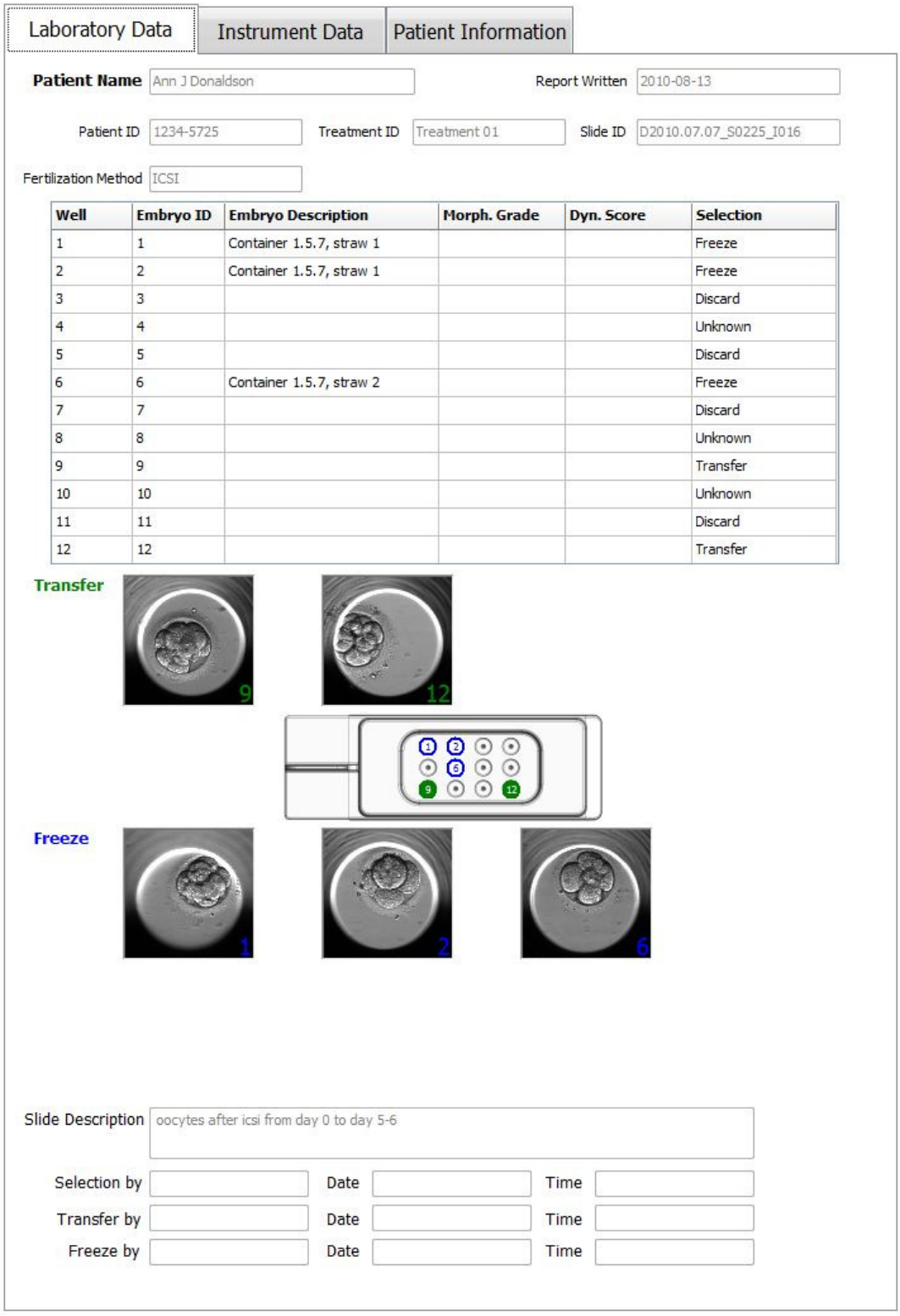


This function generates three reports based on information from the EmbryoScope™ and information from the EmbryoViewer™.

6.6.1 Laboratory data

The laboratory data sheet is used in the laboratory to obtain an overview of the selected embryos chosen for transfer and freezing. After use in the laboratory, the report can be enclosed in the patient journal. All spaces are filled out automatically, except the embryo selection spaces; these are empty and can be used for subsequently writing in initial/name of the person who performed the embryo selection, transfer and freeze.

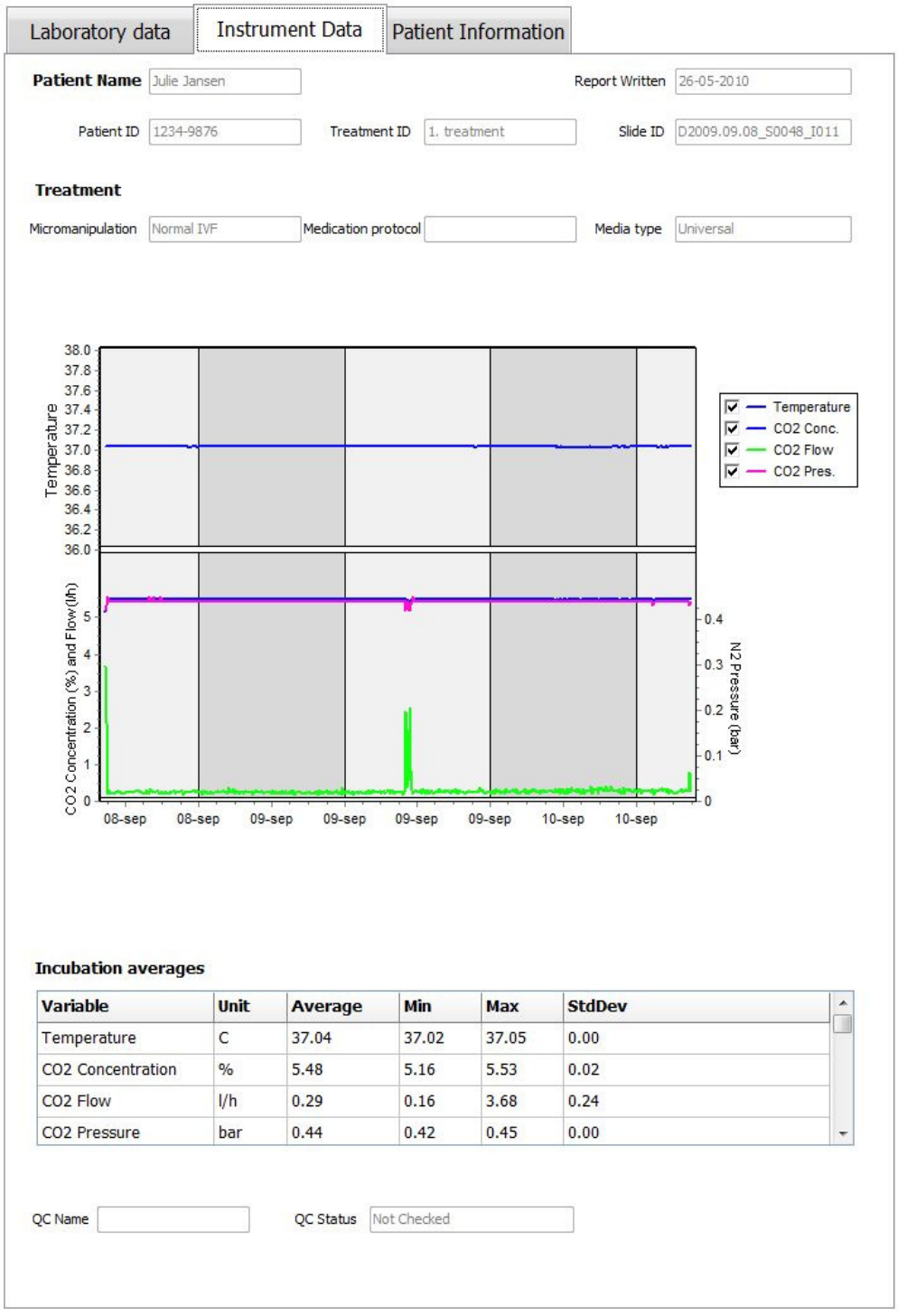
The report shows the last image of the selected and frozen embryos, and a diagram of the slide indicating the position of the selected and frozen embryos. At the top of the report patient name, patient ID, treatment ID, slide ID, fertilization method and date of report printed are shown.



Well	Embryo ID	Embryo Description	Morph. Grade	Dyn. Score	Selection
1	1	Container 1.5.7, straw 1			Freeze
2	2	Container 1.5.7, straw 1			Freeze
3	3				Discard
4	4				Unknown
5	5				Discard
6	6	Container 1.5.7, straw 2			Freeze
7	7				Discard
8	8				Unknown
9	9				Transfer
10	10				Unknown
11	11				Discard
12	12				Transfer

6.6.2 Instrument data

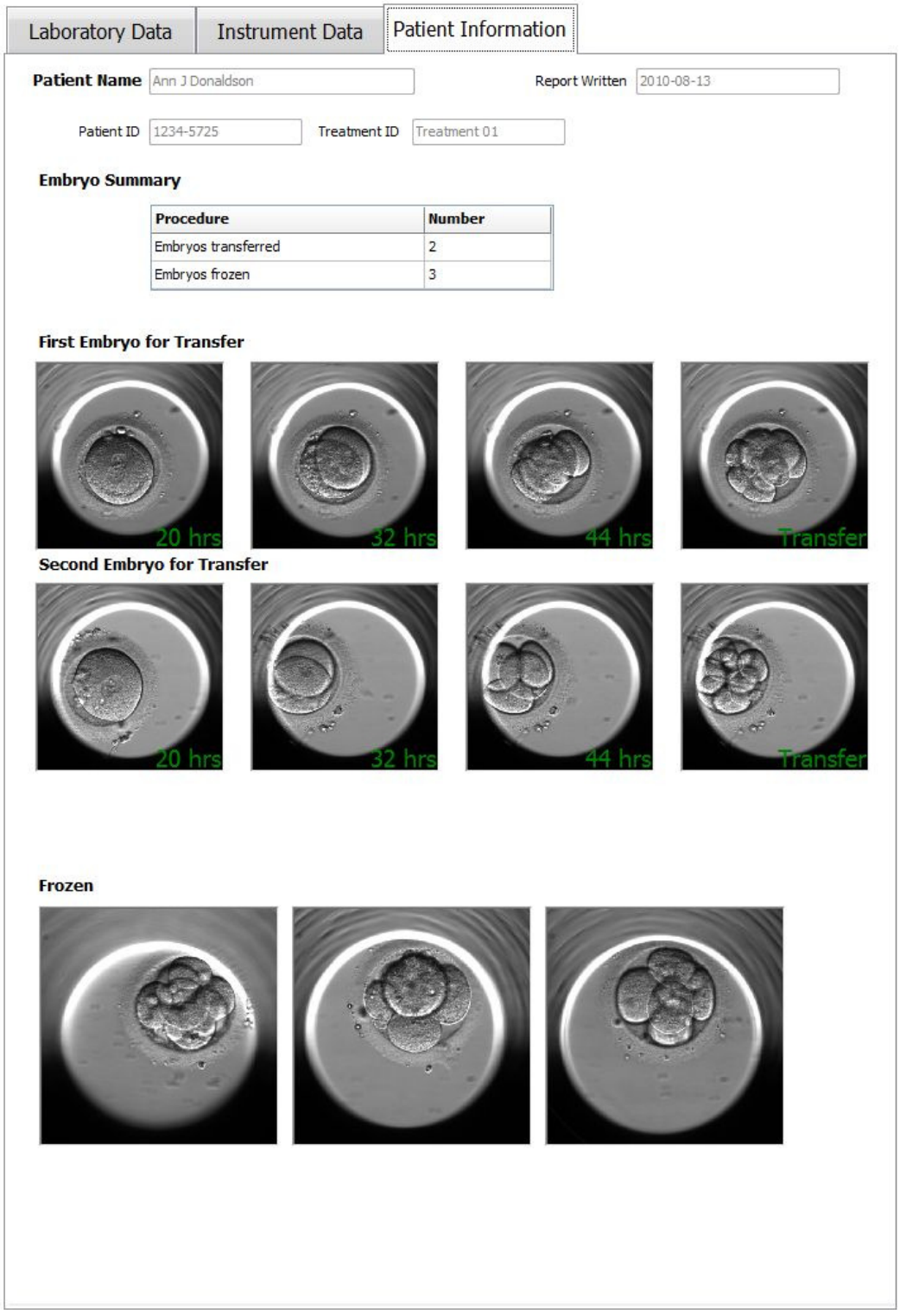
The instrument data sheet shows a table of average, min, max and standard deviations of temperature and gas conditions. Temperature and gas conditions are also shown graphically. Quality check status and initials of the QC person are also shown on the report. This report can be enclosed in the patient journal. At the top of the report patient name, patient ID, treatment ID, slide ID and date of report printed are shown.



Variable	Unit	Average	Min	Max	StdDev
Temperature	C	37.04	37.02	37.05	0.00
CO2 Concentration	%	5.48	5.16	5.53	0.02
CO2 Flow	l/h	0.29	0.16	3.68	0.24
CO2 Pressure	bar	0.44	0.42	0.45	0.00

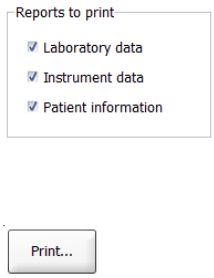
6.6.3 Patient information

The patient information sheet includes several images of transferred embryos and a single image of the frozen embryos. At the top of the report patient name, patient ID, treatment ID and date of report printed are shown. This sheet can be handed out to the patient.

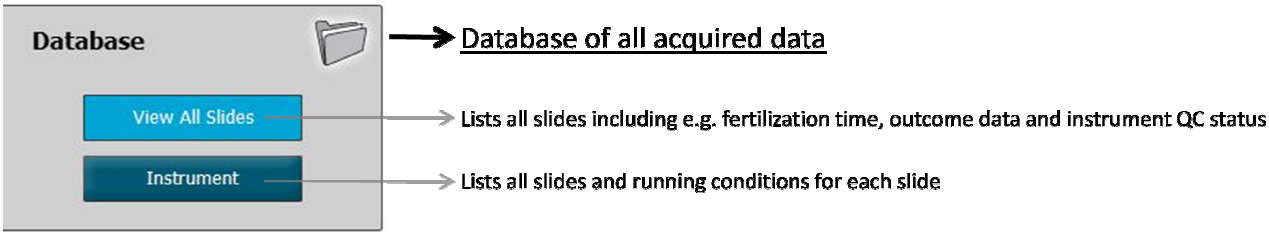


6.6.4 Print reports

Choose all or only some of the reports to be printed in the print checkbox.



7 Database


Database
View All Slides
Instrument
Database of all acquired data
Lists all slides including e.g. fertilization time, outcome data and instrument QC status
Lists all slides and running conditions for each slide

7.1 View all slides

When clicking the

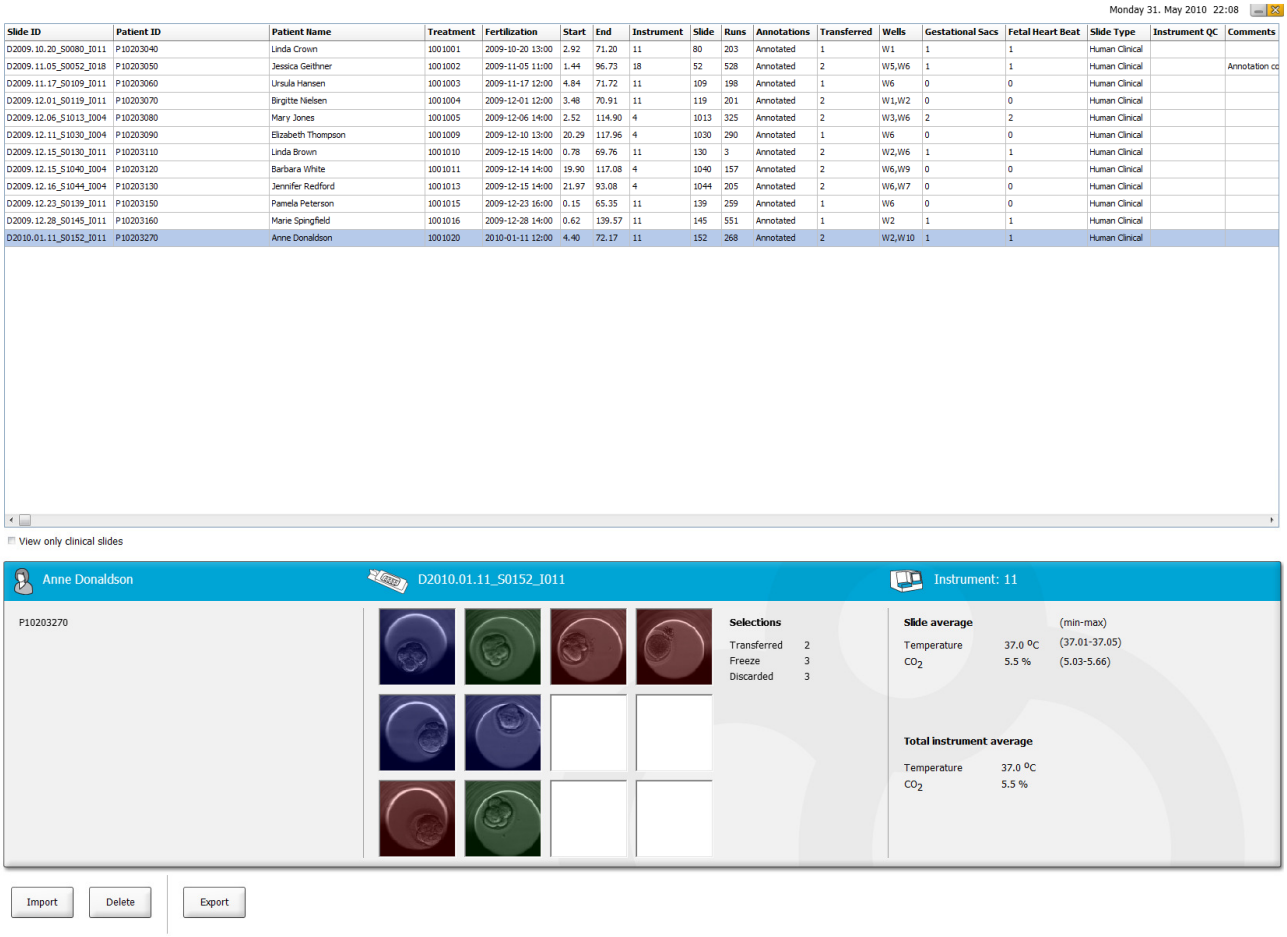
button all slides are listed with information on e.g. fertilization time, primary outcome data and instrument quality control status.

When clicking on a line it is coloured blue and throughout the EmbryoViewer™ the patient, treatment and slide belonging to the line are now active.

7.1.1 List of slides

For each slide the following parameters from the database are displayed

- Identifiers: slide ID, patient ID, patient name, treatment ID
- Fertilization time
- Start and end time of incubation in EmbryoScope™ (relative to fertilization time)
- Instrument and slide number
- Runs: Number of times images have been taken of the embryos
- Annotations: Information embryo annotation status
- Number of embryos selected for transfer from the slide and list of the wells
- Pregnancy outcome data
- Slide type
- Annotation comment and QC status


Monday 31. May 2010 22:08
Slide ID
Patient ID
Patient Name
Treatment
Fertilization
Start
End
Instrument
Slide
Runs
Annotations
Transferred
Wells
Gestational Sacs
Fetal Heart Beat
Slide Type
Instrument QC
Comments
D2009.10.20_S0080_I011 P10203040 Linda Crown 1001001 2009-10-20 13:00 2.92 71.20 11 80 203 Annotated 1 W1 1 1 Human Clinical
D2009.11.05_S0052_I018 P10203050 Jessica Geithner 1001002 2009-11-05 11:00 1.44 96.73 18 52 528 Annotated 2 W5,W6 1 1 Human Clinical Annotation co
D2009.11.17_S0109_I011 P10203060 Ursula Hansen 1001003 2009-11-17 12:00 4.84 71.72 11 109 198 Annotated 1 W6 0 0 Human Clinical
D2009.12.01_S0119_I011 P10203070 Birgitte Nielsen 1001004 2009-12-01 12:00 3.48 70.91 11 119 201 Annotated 2 W1,W2 0 0 Human Clinical
D2009.12.06_S1013_I004 P10203080 Mary Jones 1001005 2009-12-06 14:00 2.52 114.90 4 1013 325 Annotated 2 W3,W6 2 2 Human Clinical
D2009.12.11_S1030_I004 P10203090 Elizabeth Thompson 1001009 2009-12-10 13:00 20.29 117.96 4 1030 290 Annotated 1 W6 0 0 Human Clinical
D2009.12.15_S0130_I011 P10203110 Linda Brown 1001010 2009-12-15 14:00 0.78 69.76 11 130 3 Annotated 2 W2,W6 1 1 Human Clinical
D2009.12.15_S1040_I004 P10203120 Barbara White 1001011 2009-12-14 14:00 19.90 117.08 4 1040 157 Annotated 2 W6,W9 0 0 Human Clinical
D2009.12.16_S1044_I004 P10203130 Jennifer Redford 1001013 2009-12-15 14:00 21.97 93.08 4 1044 205 Annotated 2 W6,W7 0 0 Human Clinical
D2009.12.23_S0139_I011 P10203150 Pamela Peterson 1001015 2009-12-23 16:00 0.15 65.35 11 139 259 Annotated 1 W6 0 0 Human Clinical
D2009.12.28_S0145_I011 P10203160 Marie Spingfield 1001016 2009-12-28 14:00 0.62 139.57 11 145 551 Annotated 1 W2 1 1 Human Clinical
D2010.01.11_S0152_I011 P10203270 Anne Donaldson 1001020 2010-01-11 12:00 4.40 72.17 11 152 268 Annotated 2 W2,W10 1 1 Human Clinical
View only clinical slides
Anne Donaldson
D2010.01.11_S0152_I011
Instrument: 11
P10203270
Selections
Transferred 2
Freeze 3
Discarded 3
Slide average
(min-max)
Temperature 37.0 °C (37.01-37.05)
CO2 5.5 % (5.03-5.66)
Total instrument average
Temperature 37.0 °C
CO2 5.5 %
Import
Delete
Export

7.1.2 Overview of data for selected slide

The box below the list of slides gives an overview of:

- Patient data
- Embryo images: last image of each well is shown and the numbers of embryos selected for transfer, freeze and discarding are displayed
- Instrument data: average temperature and gas concentration data for the selected slide and overall for the instrument

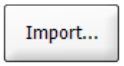
7.1.3 Filters and sorting of data

For each of the columns a menu will be opened if the header is clicked. The data can be sorted in ascending or descending order and for some of the parameters the menu includes filters to include or exclude some of the data. Filters can also be reset in the menu.

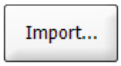
If the checkbox ☐ View only clinical slides below the list of all slides is checked, only human clinical slides are displayed in the list of slides.

7.1.4 Importing a slide

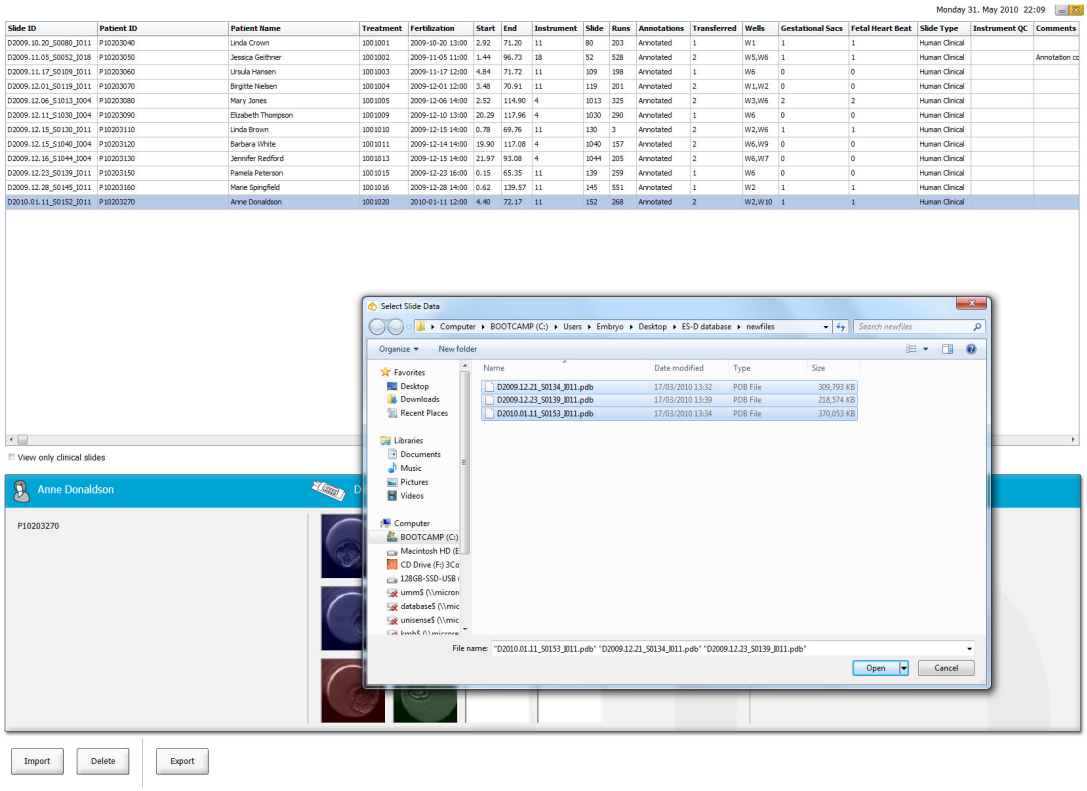
If the EmbryoScope™ is connected to the EmbryoViewer™, the finished slides are automatically imported to the database in the EmbryoViewer™.

If there is no connection the 

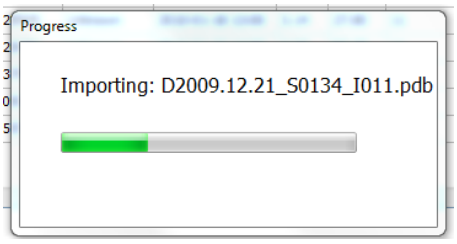
button can be used to manually import the finished slides from the EmbryoScope™ after the datafiles have been moved to the EmbryoViewer™ using for instance a USB stick.

Clicking the 

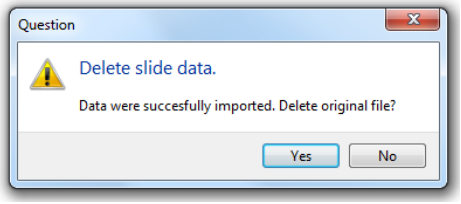
button opens a dialog box from which one or multiple slides can be imported.



A pop up box appears while slide data is imported.



After import the file with the slide data is saved in the database folder and a dialog box asks if the slide data should be deleted from the folder from where it was imported. If the slide is already present in the database a pop up box appears asking for overwriting the existing slide data or not importing the slide.



7.1.5 Deleting a slide

Clicking the Delete... button deletes highlighted slides.

7.1.6 Exporting data from the database

Clicking the Export... button exports patient data and well annotation data for highlighted slides to a Microsoft Office Excel 97-2003 worksheet.

7.2 Instrument

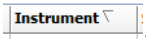
7.2.1 List of running conditions for all slides

To get an overview of all instruments, main running parameters and quality check status, click Instrument. The table lists average incubation details for all slides in the database.

- Average incubation temperature, gas concentration and flow
- QC status and comments to the QC

Slide ID	Instrument	Slide	Patient ID	Start	Temperature	CO2 Conc	CO2 Flow	O2 Conc	N2 Flow	QC	Comment
D2010.05.25_S0130_I007	7	130	2456	2010-05-25 14:06	37.019	5.351	0.145	4.573	2.373	Approved	
D2010.05.25_S0131_I007	7	131	5673-8954	2010-05-25 14:07	37.136	3.963	3.870	8.665	24.561	Approved	
D2010.05.25_S0132_I007	7	132	4562-8654	2010-05-25 14:08	37.136	3.963	3.870	8.665	24.561	Approved	
D2010.05.25_S0133_I007	7	133	2457-8754	2010-05-25 14:25	37.155	3.731	4.508	8.665	24.561	Approved	
D2010.05.25_S0134_I007	7	134	4631-9535	2010-05-25 14:26	37.155	3.731	4.508	8.665	24.561	Approved	
D2010.05.25_S0135_I007	7	135	4710-9271	2010-05-25 14:27	37.156	3.639	4.808	8.665	24.561	Approved	
D2010.05.25_S0128_I007	7	128	547689-543275	2010-05-25 13:20	37.012	5.302	0.078			Approved	
D2010.05.25_S0129_I007	7	129	125648-875367	2010-05-25 13:29	37.014	5.310	0.077			Approved	
D2010.05.25_S0130_I007	7	130	2456	2010-05-25 14:06	37.019	5.351	0.145	4.573	2.373	Approved	
D2010.05.25_S0131_I007	7	131	5673-8954	2010-05-25 14:07	37.136	3.963	3.870	8.665	24.561	Approved	
D2010.05.25_S0132_I007	7	132	4562-8654	2010-05-25 14:08	37.136	3.963	3.870	8.665	24.561	Approved	
D2010.05.25_S0133_I007	7	133	2457-8754	2010-05-25 14:25	37.155	3.731	4.508	8.665	24.561	Approved	
D2010.05.25_S0134_I007	7	134	4631-9535	2010-05-25 14:26	37.155	3.731	4.508	8.665	24.561	Approved	
D2010.05.25_S0135_I007	7	135	4710-9271	2010-05-25 14:27	37.156	3.639	4.808	8.665	24.561	Approved	
Average					**37.05**	**4.75**	**1.84**	**7.98**	**20.86**		

7.2.2 Average incubation conditions for all slides

The average incubation temperature, gas concentration and flow for all, several or a specific instrument is calculated at the bottom of the table. The average incubation conditions for a specific instrument are calculated by selecting the instrument in the top row 

. All other parameters can be sorted in ascending or descending order by clicking on the top row.

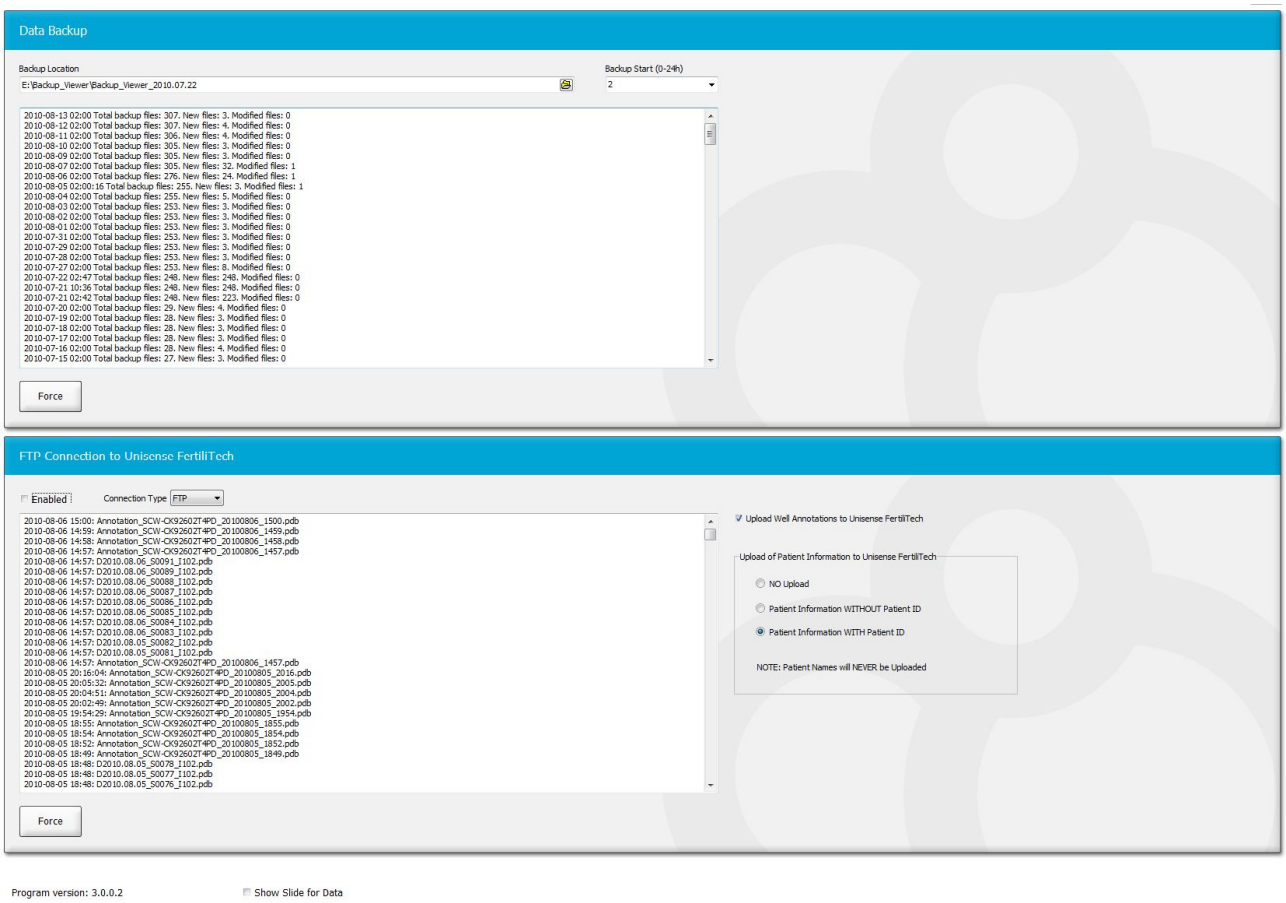
D2010.08.06_S0083_I102	102	83	P0014	2010-08-06 10:28	37.047	4.243	5.050	6.458	14.162
D2010.08.06_S0084_I102	102	84	P0015	2010-08-06 10:29	37.047	4.243	5.050	6.458	14.162
D2010.08.06_S0085_I102	102	85	P0016	2010-08-06 10:35	37.049	-1.000	-1.000	6.732	16.011
D2010.08.06_S0086_I102	102	86	P0016	2010-08-06 10:35	37.049	-1.000	-1.000	6.732	16.011
Average					**37.07**	**5.35**	**0.84**	**5.35**	**10.18**

8 Settings

8.1 Backup and upload of data to Unisense FertiliTech A/S

Clicking

opens a page with two frames, one related to backup of data in the database and one related to upload of data to Unisense FertiliTech A/S.

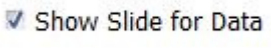

Data Backup
Backup Location
E:\Backup_Viewer\Backup_Viewer_2010.07.22
Backup Start (0-24h)
2
2010-08-13 02:00 Total backup files: 307. New files: 3. Modified files: 0
2010-08-12 02:00 Total backup files: 307. New files: 4. Modified files: 0
2010-08-11 02:00 Total backup files: 306. New files: 4. Modified files: 0
2010-08-10 02:00 Total backup files: 305. New files: 3. Modified files: 0
2010-08-09 02:00 Total backup files: 305. New files: 3. Modified files: 0
2010-08-07 02:00 Total backup files: 305. New files: 32. Modified files: 1
2010-08-06 02:00 Total backup files: 276. New files: 24. Modified files: 1
2010-08-05 02:00:16 Total backup files: 255. New files: 3. Modified files: 1
2010-08-04 02:00 Total backup files: 255. New files: 5. Modified files: 0
2010-08-03 02:00 Total backup files: 253. New files: 3. Modified files: 0
2010-08-02 02:00 Total backup files: 253. New files: 3. Modified files: 0
2010-08-01 02:00 Total backup files: 253. New files: 3. Modified files: 0
2010-07-31 02:00 Total backup files: 253. New files: 3. Modified files: 0
2010-07-29 02:00 Total backup files: 253. New files: 3. Modified files: 0
2010-07-28 02:00 Total backup files: 253. New files: 3. Modified files: 0
2010-07-27 02:00 Total backup files: 253. New files: 8. Modified files: 0
2010-07-22 02:47 Total backup files: 248. New files: 248. Modified files: 0
2010-07-21 10:36 Total backup files: 248. New files: 248. Modified files: 0
2010-07-21 02:42 Total backup files: 248. New files: 223. Modified files: 0
2010-07-20 02:00 Total backup files: 29. New files: 4. Modified files: 0
2010-07-19 02:00 Total backup files: 28. New files: 3. Modified files: 0
2010-07-18 02:00 Total backup files: 28. New files: 3. Modified files: 0
2010-07-17 02:00 Total backup files: 28. New files: 3. Modified files: 0
2010-07-16 02:00 Total backup files: 28. New files: 4. Modified files: 0
2010-07-15 02:00 Total backup files: 27. New files: 3. Modified files: 0
Force
FTP Connection to Unisense FertiliTech
Enabled
Connection Type
FTP
2010-08-06 15:00: Annotation_SCW-CK92602T4PD_20100806_1500.pdb
2010-08-06 14:59: Annotation_SCW-CK92602T4PD_20100806_1459.pdb
2010-08-06 14:58: Annotation_SCW-CK92602T4PD_20100806_1458.pdb
2010-08-06 14:57: Annotation_SCW-CK92602T4PD_20100806_1457.pdb
2010-08-06 14:57: D2010.08.06_S0091_1102.pdb
2010-08-06 14:57: D2010.08.06_S0089_1102.pdb
2010-08-06 14:57: D2010.08.06_S0088_1102.pdb
2010-08-06 14:57: D2010.08.06_S0087_1102.pdb
2010-08-06 14:57: D2010.08.06_S0086_1102.pdb
2010-08-06 14:57: D2010.08.06_S0085_1102.pdb
2010-08-06 14:57: D2010.08.06_S0084_1102.pdb
2010-08-06 14:57: D2010.08.06_S0083_1102.pdb
2010-08-06 14:57: D2010.08.05_S0082_1102.pdb
2010-08-06 14:57: D2010.08.05_S0081_1102.pdb
2010-08-06 14:57: Annotation_SCW-CK92602T4PD_20100806_1457.pdb
2010-08-05 20:16:04: Annotation_SCW-CK92602T4PD_20100805_2016.pdb
2010-08-05 20:05:32: Annotation_SCW-CK92602T4PD_20100805_2005.pdb
2010-08-05 20:04:51: Annotation_SCW-CK92602T4PD_20100805_2004.pdb
2010-08-05 20:02:49: Annotation_SCW-CK92602T4PD_20100805_2002.pdb
2010-08-05 19:54:29: Annotation_SCW-CK92602T4PD_20100805_1954.pdb
2010-08-05 18:55: Annotation_SCW-CK92602T4PD_20100805_1855.pdb
2010-08-05 18:54: Annotation_SCW-CK92602T4PD_20100805_1854.pdb
2010-08-05 18:52: Annotation_SCW-CK92602T4PD_20100805_1852.pdb
2010-08-05 18:49: Annotation_SCW-CK92602T4PD_20100805_1849.pdb
2010-08-05 18:48: D2010.08.05_S0078_1102.pdb
2010-08-05 18:48: D2010.08.05_S0077_1102.pdb
2010-08-05 18:48: D2010.08.05_S0076_1102.pdb
Force
Upload Well Annotations to Unisense FertiliTech
Upload of Patient Information to Unisense FertiliTech
NO Upload
Patient Information WITHOUT Patient ID
Patient Information WITH Patient ID
NOTE: Patient Names will NEVER be Uploaded
Program version: 3.0.0.2
Show Slide for Data

8.1.1 EmbryoViewer™ software version

Below the backup and data upload boxes the version number of the EmbryoViewer™ software is shown.

8.1.2 Slides for data agreement

If the Fertility Clinic has signed a "Slides for Data Agreement" a check box can be clicked.

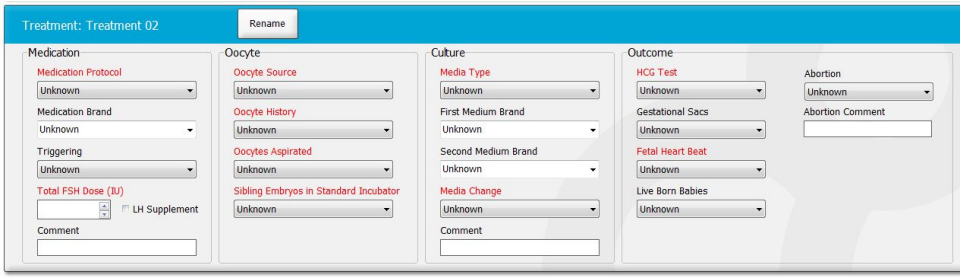


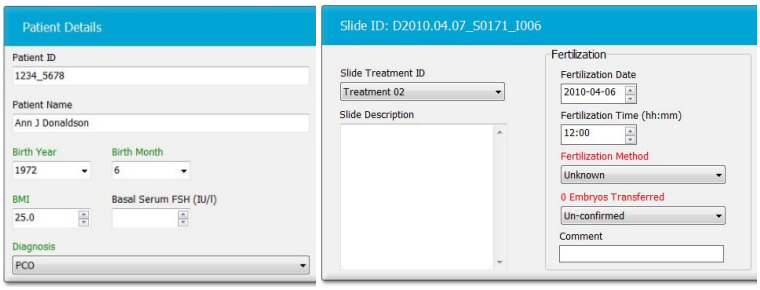
This enables an easy overview on the "View All Slides" and "Patient Details" pages of the number of slides where the conditions for slide cost reimbursement are fulfilled ("View All Slides") and of the amount of data necessary to upload to fulfill the "Slides for Data Agreement" ("Patient Details").

On the "View All Slides" page all slides where the "Slides for Data Agreement" conditions are fulfilled are colored green.

Slide ID	Patient ID	Patient Name	Treatment ID	Fertilization	Start (h)	End (h)
D2010.04.07_S0170_I006	1234_5678	Ann J Donaldson	Treatment 01	2010-04-06 12:00	25.73	25.90
D2010.04.07_S0171_I006	1234_5678	Ann J Donaldson	Treatment 02	2010-04-06 12:00	26.14	26.51

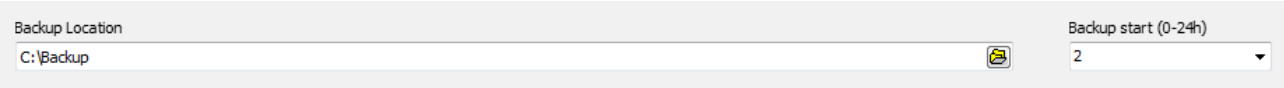
On the "Patient Details" page all information that are necessary to provide by the Fertility Clinic to fulfill the "Slides for Data Agreement" are colored red, and when the information is inserted the text is colored green, see examples below.



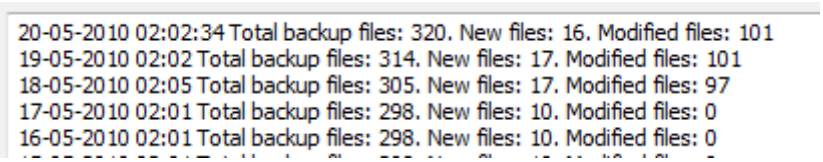


8.2 Data backup

Data backup includes backup of the slide database and backup of the main and patient database. It is possible to specify both a backup location and a backup time.



Data backup are performed daily on the specified time. Backup files are listed with date and time.


20-05-2010 02:02:34 Total backup files: 320. New files: 16. Modified files: 101
19-05-2010 02:02 Total backup files: 314. New files: 17. Modified files: 101
18-05-2010 02:05 Total backup files: 305. New files: 17. Modified files: 97
17-05-2010 02:01 Total backup files: 298. New files: 10. Modified files: 0
16-05-2010 02:01 Total backup files: 298. New files: 10. Modified files: 0

Clicking

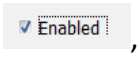
performs a forced data backup. A forced data backup creates an extra backup file and does not affect the daily data backup.

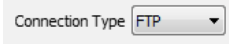
WARNING:

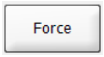
Backup of image and patient data MUST be performed at regular intervals. Automated nightly backups to a safe external hard disc can be implemented through a selection in the settings tab.

8.3 FTP connection to Unisense FertiliTech A/S

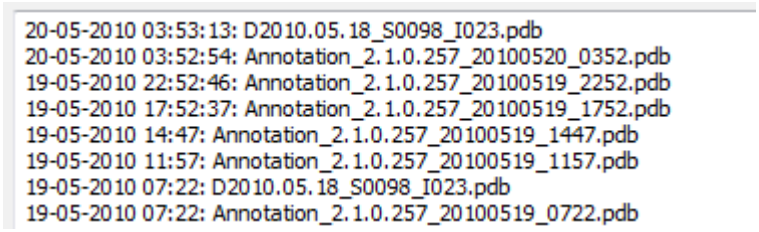
It is possible for users to upload anonymous treatment data (images, temperature and gas readings, procedure, outcome etc.) to a secure FTP server at Unisense FertiliTech A/S to facilitate quality control and off site quality control. Users have expressed an interest in a built-in feature to do this automatically every night. Unisense FertiliTech A/S will keep the data on a secure server, and will not distribute the data. The sole use of the data will be to evaluate if the instrument is operating properly and to report back to the clinic if any advance sign of irregularities are observed. Unisense FertiliTech A/S intends to do a technical review of the uploaded data on a regular basis, but will not be obliged to do so. By uploading the data to Unisense FertiliTech A/S the clinic will grant Unisense FertiliTech A/S the permission to use information derived from the data to improve future products free of charge/royalties to the entities that have uploaded the data.

It is possible to automatically upload new data to a Unisense FertiliTech A/S FTP server every night by selecting 

, the type of connection is specified 

. When there is new data to upload, the data is uploaded to Unisense FertiliTech A/S. If the internet connection has been lost, a forced upload of data can be performed by clicking 

. Uploaded files are listed with date and filename.



RESTRICTIONS ON USE:

The clinic shall be solely responsible for ensuring that all local rules and regulations are observed in connection with the upload of data to Unisense FertiliTech A/S and that patients are informed about such upload of data.

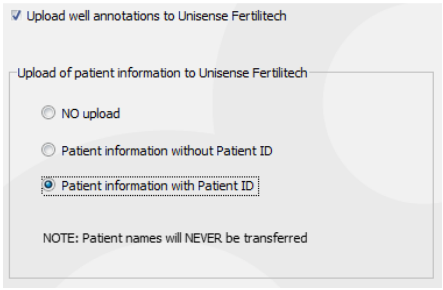
RESTRICTIONS ON USE:

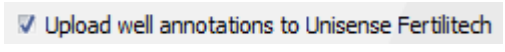
Upload of data may only be initiated IF THIS IS PERMISSIBLE BY LAW AND REGULATIONS in the country where the EmbryoViewer™ resides.

8.3.1 Data uploaded to Unisense FertiliTech A/S

Data can be uploaded with different levels of information.

NOTE: Information from the variable “Patient Name” will never be uploaded.


Upload well annotations to Unisense Fertilitech
Upload of patient information to Unisense Fertilitech
NO upload
Patient information without Patient ID
Patient information with Patient ID
NOTE: Patient names will NEVER be transferred

- 

Upload only slide data, this includes embryo images, embryo annotation e.g. cleavage patterns, an auto generated slide ID number, running conditions.

8.3.2 Patient information uploaded to Unisense FertiliTech A/S

- NO upload No patient information is uploaded
- Patient information without Patient ID Upload slide data (see above) and patient treatment and outcome data without uploading data from the "Patient ID" variable
- Patient information with Patient ID Upload slide data (see above) and patient treatments and outcome data including data from the "patient ID" variable (information from the variable "Patient Name" is never uploaded)

RESTICTIONS ON USE:

Only anonymous data may be uploaded to Unisense FertiliTech A/S.
Patient ID may only be uploaded if the ID number is an internal number used by the fertility clinic. If the patient ID is a social security number of any other traceable personal ID number it may NOT be uploaded to Unisense FertiliTech A/S

9 Acknowledgements

All identification numbers, names and treatment data presented in this manual is purely fictive.
We acknowledge IVI Valencia, Spain and Marcos Meseguer for providing the embryo images.

10 Disposal of waste

Identification of risks associated with the disposal of the EmbryoViewer™ and its accessories. In order to minimize the waste of electrical and electronic equipment, waste is disposed according to the Directive 2002 / 96 / EC – Waste Electrical & Electronic Equipment (WEEE).

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